Office - Supreme Court, U.S.
FILED
FEB 4 1953
HAROLD B. WILLEY, Clerk

GLY-H
18

IN THE

Supreme Court of the United States

OCTOBER TERM, 1952

No. 584.

GLYCO PRODUCTS CO., INC., *Petitioner,*

v.

FEDERAL SECURITY ADMINISTRATOR, *Respondent.*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

MICHAEL F. MARKEL,
522 Munsey Building,
Washington 4, D. C.,
Attorney for Petitioner.

WAYNE K. HILL,
Of Counsel.

PRESS OF BYRON S. ADAMS, WASHINGTON, D. C.

INDEX.

	Page
OPINION BELOW	1
JURISDICTION	1
QUESTIONS PRESENTED	2
STATUTE INVOLVED	3
STATEMENT	5
SPECIFICATION OF ERRORS TO BE URGED	10
REASONS FOR GRANTING THE WRIT	11
CONCLUSION	25

CITATIONS.

CASES:

Federal Security Administrator v. *Quaker Oats Co.*, 318 U. S. 218, 63 S. Ct. 589 (1943) 10, 16-19

Land O'Lakes Creameries, Inc. v. *McNutt*, 132 F. 2d 653 (1943) 16, 22

Libby, McNeil and Libby v. *United States*, 148 F. 2d 71 (1945) 16, 22

Quaker Oats Company v. *Federal Security Administrator*, 129 F. 2d 76 18-19

62 Cases . . . Jam v. *United States*, 340 U. S. 593, 71 S. Ct. 515 (1951) 16

Youngstown Sheet and Tube Co. et al. v. *Sawyer*, 343 U. S. 579, 72 S. Ct. 863 (1952) 23-24

MISCELLANEOUS:

Dunn, Federal Food, Drug, and Cosmetic Act (1938) 13-15

APR 21 1954

205383

IN THE

Supreme Court of the United States

OCTOBER TERM, 1952

No. .

GLYCO PRODUCTS CO., INC., *Petitioner,*

v.

FEDERAL SECURITY ADMINISTRATOR, *Respondent.*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Glyco Products Co., Inc., prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Third Circuit entered in the above-entitled case on December 22, 1952.

OPINION BELOW

The Court of Appeals rendered an opinion (R. p. 757) which is not as yet officially reported.

JURISDICTION

The judgment of the Court of Appeals was entered on December 22, 1952. The jurisdiction of this Court is invoked under 28 U.S.C.A. § 1254 (1).

QUESTIONS PRESENTED

1. Whether the authority to "promulgate regulations fixing and establishing * * * a *reasonable* definition and standard of identity" for a food, conferred upon the respondent by Section 401 of the Federal Food, Drug, and Cosmetic Act, includes authority to specify and limit, by regulation promulgated pursuant to *this* Section, those substances which *need* not, but *may* be added to a standardized food, *not* to achieve economic integrity, but to practice the inherent *culinary art* according to the preferences of the individual food manufacturer; not ultimately included upon the basis of any administrative "judgment" that one or more of these ingredients is in fact required to insure food honesty, but upon the basis of the "judgment" of the regulated food fabricator, or his chef, founded on *their* belief that their customers will prefer this *standard* food when it possesses the organoleptic characteristics imparted to it by the presence therein of such a permitted substance, and, if so—

2. Does the delegation of legislative functions to the respondent by Section 401, as construed by the court below, meet constitutional requirements as to certainty in its delineation of such functions since the administrative action compiling a list of *permissive* ingredients does not rest on considerations of any defineable economic integrity of the food being standardized and since the ultimate decision as to whether one or more of these permissive ingredients should be added to such food is made, not on the basis of administrative judgment, but on the basis of the judgment of the individual food processors and; if constitutional as thus construed—

3. Whether the respondent, in the exercise of his administrative powers under Section 401, defined in most *general* terms, may exclude such ingredients from his list of *permitted* ingredients on the basis of an ultimate conclusion of fact of likely consumer deception or health haz-

ard, in the presence of *specific* and detailed provisions of other sections of the Act *specifically* calculated to protect consumers against these risks and, by electing to standardize a food, dodge Government responsibility for enforcing Sections 402(a)(1) & (2), as supplemented by Section 406, and Section 402(b) of the Act and avoid the Government's statutory burden of affirmative proof of these issues of fact in court to the satisfaction of the judge or jury, at the same time depriving the food manufacturer of his right to have them tried by judge or jury and imposing on him the much greater burden of establishing the *negative* thereof to the *respondent's* satisfaction.

4. Do the respondent's stated grounds for refusing to specify polyoxyethylene monostearate as a permissive ingredient in his regulation, constitute a lawful basis for his administrative action having the legal effect (if his construction of the provisions of Section 401 of the Act be correct) of closing a vast market to this product, since his negative findings of insufficiency of proof are not related to any record supported findings prescribing a reasonably specific standard of adequacy of proof, or reference standard?

STATUTE INVOLVED

The pertinent statutory provisions involved are included in Section 401, Section 402(a)(1) and (2), as implemented by Section 406(a), and Section 402(b), of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), 21 U.S.C. §§ 341, 342(a)(1) and (2), 346(a), and 342(b), as follows—

> "Sec. 401. Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, * * *. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Administrator shall, for the purpose of promoting honesty and fair dealing in the in-

terest of consumers, designate the optional ingredients which shall be named on the label, * * *."

* * * * * * *

"Sec. 402. A food shall be deemed to be adulterated—

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; * * *."

* * * * * * *

"Sec. 406. (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402(a); but when such substance is so required or cannot be so avoided, the Administrator shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402(a) * * *."

* * * * * * *

Section 402. A food shall be deemed to be adulterated—

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or *make it appear better or of greater value than it is.*" (Italics ours)

STATEMENT

This petitioner challenges the validity of the respondent's order promulgating regulations fixing and establishing definitions and standards of identity for bread and certain other specified bakery products, to the extent to which the administrative action thus taken attempts to deny the further use in such bakery products of polyoxyethylene monostearate, a substance manufactured and marketed by this petitioner and now widely used in many bakery products, including those which are the subject of the challenged order.

The challenged order was issued pursuant to the provisions of Section 401 of the Federal Food, Drug, and Cosmetic Act [52 Stat. 1046 (1938), 21 U.S.C. § 341], quoted in pertinent part above. It is based on the record made at a public hearing, consisting of a series of sessions, held in compliance with the prescribed procedural requirements of Section 701(e) of that Act [52 Stat. 1055 (1938), 21 U.S.C. § 371(e)].

The hearing was commenced pursuant to notice, which included the respondent's proposed regulation, as published in the Federal Register for June 7, 1941 (6 F. R. 2771). However, due to the intervention of war and for other reasons, the hearing was suspended without any fixed date for its resumption. It was resumed in the fall of 1948 pursuant to the respondent's notice as published in the Federal Register for October 14, 1948 (13 F. R. 6024). Reception of evidence pursuant to this second notice was expanded so as to include consideration of certain surface-active agents, including polyoxyethylene monostearate manufactured and marketed by this petitioner, which had come into general use as ingredients for bakery products since the 1941 proposal. The respondent thus brought up for consideration at this hearing the question of suitability of these and other similar substances for use in bread and the other specified bakery products. The petitioner appeared at this public hearing pursuant to said respondent's notice and proposal

and, together with other manufacturers of like products, presented evidence calculated to establish both the safety and suitability of their products as such ingredients.

The record made pursuant to the second notice over a period of about eleven months consists of upwards of 17,000 pages, exclusive of exhibits. The vast majority of this record consists of testimony bearing on the questions of suitability and safety of polyoxyethylene monostearate for use as such an ingredient. Much of this testimony was offered by and through representatives of manufacturers of competing ingredients. The respondent, who had available to him a highly qualified technical staff, presented no evidence on these issues.

The quantity of polyoxyethylene monostearate required in bread to achieve the desired bread characteristics is never in excess of 0.5% (Finding 39). The respondent has found that its function, when so used, is to keep bread *softer* longer (Finding 39). In his proposed Finding 42 (15 F.R. 5107) he found further that such use "may enable consumers to keep such bread longer before it becomes *unpalatable.*" Petitioner contended (and still claims) that it keeps bread *fresh* longer and that preservation of palatability and softness, as found by the respondent, amounted to a finding of preservation of freshness. Rather than debate this question, the respondent changed his mind as to the characteristics produced by our ingredient and changed his final finding to read "may enable consumers to keep such bread longer before it *hardens.*" In any case, while the respondent's findings betray considerable indecision as to the functional properties of our ingredient when used up to 0.5% in bread, he makes no finding showing that such use has any bearing on the "standard of identity" of bread, but rather shows affirmatively that it only imparts organoleptic characteristics to the bread. His regulation fixing and establishing a definition and standard of identity, *requires* only the following—

"§ 17.1. * * * (a) Each of the foods bread, white bread, rolls, white rolls, buns, white buns is prepared by baking *a kneaded yeast-leavened dough, made by moistening flour with water or with one or more of the optional liquid ingredients specified in this section* [the several kinds of milk] *or with any mixture of water and one or more of such ingredients.* * * * *Each of such foods is seasoned with salt*, and in its preparation one or more of the optional ingredients prescribed by subparagraphs (1) to (14), inclusive, of this paragraph *may* be used:

* * * * * *

"Each of such foods contains *not less than 62 percent of total solids,* * * *.*" (Italics ours)

The requirements of the last phrase is another way of saying that these bakery products must not contain more than 38% moisture as a finished product; an essential bread component required to be so limited since retention of excess water in bread is one of the common forms of chiseling and bread adulteration. (Finding 4.)

All ingredients not specified in the quoted part of the standard are *permissive* and may be used, or omitted, as dictated by the *baker's* and *not* the respondent's judgment. Petitioner's product is in the latter category.

This petitioner also challenged the respondent's jurisdiction to resolve the issues of fact raised by his consideration of petitioner's product. Jurisdiction was challenged on the grounds that (a) the functional properties of the petitioner's product had no bearing on the standard of identity as proposed to be fixed for the bakery products under consideration and, (b) the issues thus raised were required to be resolved by a court or jury in proceedings initiated in the enforcement of Sections 402 (a)(1) & (2), as implemented by Section 406, and Section 402(b) of the Act. [Exceptions to proposed order: R. pp. 1a-23a].

The respondent denied our objection to jurisdiction and declined to specify petitioner's product as a *permissive* in-

gredient in his regulation on the grounds specified in Findings 38 to 42 inclusive. They add up to two basic reasons—

(1) That its presence in these bakery products serves to make them appear better or of greater value than they are in that the softness achieved thereby tends to deceive consumers as to the age of bread; and

(2) That "although the record shows no definite evidence of injury from the use of * * * polyoxyethylene monostearate in the amounts in which they are likely to occur in the diet from their use in bread, results of the pharmacological tests reported do not warrant the conclusion that there is no likelihood of injury from bread containing these substances in the amounts proposed to persons consuming it continuously over a life span" (Finding 42); *i. e.*, it has not been established to respondent's satisfaction that such bread may not be dangerous to health.

There should also be noted as part of this statement, the administrative construction of Section 401 and the consequent pattern of food standards, in order to point up the questions here raised and their general importance to the food industry and to consumers.

The respondent has interpreted the provisions of Section 401 to include a grant of power to him to establish, in his regulations fixing and establishing definitions and standards of identity for foods, two classes of optional ingredients: (1) two or more ingredients specified as *mandatory* from which a producer is allowed, at his option, to select but is *required* to use one thereof in order to insure the standard of identity, or standard of economic integrity, fixed and established by the regulation, and (2) a list of ingredients also characterized as "optional", none of which a producer is *required* to use, but which he *may* use, depending entirely on his own wishes dictated by his own judgment as to the organoleptic food characteristics preferred by his customers.

Thus a loaf of bread which, according to the expressed judgment of the respondent, "will promote honesty and fair dealing in the interest of consumers," is one baked from a salted, yeast-leavened dough prepared from one of the kinds of flours specified and baked to a degree so that the finished loaf will not contain more than 38% of moisture. The use of all other ingredients specified is left entirely to the baker's judgment in the practice of his art of baking. A standard fruit preserve need only contain fruit and sugar, or a mixture of sugars, as the essential ingredients in the prescribed ratio and be concentrated to a specified degree so as to prevent excess water. All the remaining ingredients, including vinegar, lemon juice, lime juice, citric acid, lactic acid, pectin, sodium citrate, sodium benzoate and others, are *permissive* and not *required.* (21 C.F.R. § 29.0)[1]

The petitioner challenges the correctness of a construction of the provisions of Section 401 which authorizes promulgation of this type of standard, and, if such be its meaning, the constitutionality of such a broad delegation of administrative power. It contends that the provisions of Section 401 merely authorize the Administrator to *fix* the ingredients required to insure the *identity* of the food under a specified name, and to *establish a standard of identity* for such food by fixing the ratio for these ingredients; that is, by fixing floors for the expensive and ceilings for the cheaper of such required ingredients at levels so as to insure a food of an economic integrity which may reasonably be expected of such food when sold under the specified name.

The petitioner duly filed its petition seeking review of the respondent's said order by the United States Court of Appeals for the Third Circuit. That court affirmed the order by judgment entered on December 22, 1952. It ren-

[1] For a complete list of federal food standards promulgated to date, see 21 C.F.R. Parts 14-53, inclusive.

dered an accompanying opinion in which the questions presented were considered and resolved against this petitioner. The court below rests its conclusions principally, if not solely, on statements included in this Court's opinion rendered in *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U. S. 218, 63 S. Ct. 589 (1943).

SPECIFICATION OF ERRORS TO BE URGED

The Court of Appeals erred:

(1) In holding that the respondent's authority by virtue of Section 401 of the Act includes the authority to deny, by administrative action under Section 401, the use of this petitioner's product as an ingredient in the bakery products which are the subject of his order.

(2) In holding that the respondent may lawfully, by virtue of Section 401, determine administratively, and as a basis for his action, factual issues of likely deception and health hazard in the presence of the specific provisions of Section 402(a)(1) & (2), as implemented by Section 406(a), and Section 402(b), specifically calculated to protect consumers against these risks.

(3) In holding that the functions delegated by Section 401, as administratively interpreted, is a constitutional delegation of legislative powers.

(4) In holding that the respondent's stated grounds for his refusal to specify polyoxyethylene monostearate as a permissive ingredient in his regulation, constitutes a valid basis for such administrative action.

(5) In refusing to decide whether the findings with respect to deception alone, or with respect to health hazards alone, constitute an adequate justification for the administrative action of excluding petitioner's product from said bakery products.

(6) In holding that the respondent's conclusion of likely consumer deception reasonably requires that this petition-

er's product be excluded from the bakery products which are the subject of said order, without any finding that such deception may not be overcome by appropriate label designation.

(7) In that it has failed and refused, in the exercise of the jurisdiction conferred upon it by Section 701(f)(3) of the Act, to set aside, permanently, that part of the respondent's order calculated to deny the use of the petitioner's product as an ingredient in the bakery products which are the subject of the challenged order.

REASONS FOR GRANTING THE WRIT

The fundamental issues raised in this case should be finally resolved by this Court in order to settle questions of importance to consumers, food manufacturers, as well as the Government.

I.

It is imperative that the scope of the legislative powers conferred upon the Administrator by Section 401 of the Act be finally determined and delineated by this Court so that all concerned may understand clearly the kind of standards contemplated and, if these be impracticable, the statutory amendments required to insure a practicable program of food standardization.

The legislative history of Section 401 shows that this legislation was in response to Government request as well as demands from consumer groups and from important segments of the regulated industry. Such legislation was said to be necessary in order to enable the Government to enforce the economic adulteration provisions of the old law more effectively and thus to protect food manufacturers against unfair methods of competition resulting from food dilution by chiseling competitors and to protect consumers against the resultant deception, since they could not differentiate, for example, between fruit preserves containing 45% fruit and one containing only 25%.

The existence of the need for administrative food standards for the protection of consumers and honest industry is still recognized today. However, both of these interests have not been afforded the effective protection contemplated because the whole standard-making program has bogged down. This is apparent from the fact that after fifteen years of effort many foods still remain on the list of foods originally scheduled for standardization within two years from the enactment of the law. Several factors have contributed to this situation, including the intervention of war. However, it is generally conceded by those concerned with food standardization that one of the important factors responsible for the development of this situation is the adoption of the administrative policy to promulgate definitions and standards of identity which are, in effect, recipes, rather than standards which will insure the presence in a food sold under a given name, the kind and quantities of ingredients required to conform to the identity expected under that name. The basic questions raised in the case go to the very heart of this problem.

That a serious question does exist as to the correctness of the administrative construction of Section 401 and the validity of the consequent pattern of food standardization followed from the beginning, is amply supported by the legislative history itself.[2] For example, one of the more persuasive arguments before congressional committees was made by producing certain examples of the kind of foods which were regarded as dishonest foods but which could not be reached by enforcement of the adulteration sections of the old law, substantially the same as those of the present law, because of the lack of commercial standards of sufficient certainty so that they could be accepted as legal standards by the courts in enforcement proceedings. The

[2] H. Rep. No. 493, 73d Cong., 2d Sess.; H. Rep. No. 361, 74th Cong., 1st Sess.; S. Rep. No. 646, 74th Cong., 1st Sess.; H. Rep. No. 2755, 74th Cong., 2d Sess.; S. Rep. No. 91, 75th Cong., 1st Sess.; H. Rep. No. 2139, 75th Cong., 3d Sess.

example most frequently referred to and which impressed congressional committees most was a substandard fruit preserve marketed as "Bred-Spred."

The problem thus illustrated and which Congress undertook to reach by enacting Section 401 is probably best pointed up by the testimony of Walter G. Campbell, then the Chief of the Food and Drug Administration. On December 7, 1933, he testified before a sub-committee of the Senate Committee on Commerce in part as follows—

> "Here is a product labeled 'Bred Spred' which has the appearance of a preserve. Investigation of the retail market showed that it was actually sold as a preserve or as a jam, but it contains less than one-half the amount of fruit required by the standard recognized by the Department for such products. The sale to the public of an article of this sort, bearing in mind that the most expensive ingredient in jams and preserves is the fruit content, is obviously a fraud upon the public. To the extent that such products can be prepared and sold, containing less than one-half the amount of fruit expected by the purchaser, used by manufacturers generally and established as a trade custom, it likewise deprives the farmer of a legitimate market for his fruit.
>
> "Compare the article marked as 'Bred Spred' with this standard jam or preserve, which contains the full 45 percent of fruit required. Their appearance is identical. They are sold in glass containers which characterize this class of products; and I submit to you that the consumer, even though a discriminating buyer, in almost every instance would be perfectly willing to accept either as a pure preserve. As a matter of fact, the price for which the article known under the distinctive name 'Bred Spred' was sold, was only slightly less than that of the product sold under the label of pure preserves."[3]

Later, Mr. Campbell illustrated the same point by another example. He said—

---

[3] Senate Hearings on S. 1944, 73d Cong., 2d Sess.; *Dunn*, Federal Food Drug, and Cosmetic Act, p. 1052.

"MR. CAMPBELL. * * * We have a number of exhibits here. I regret to take up so much time because I know how anxious you are to expedite this hearing, but I think I have here something that should be brought to your attention, Mr. Chairman. *These are samples of a mixture of chicken and noodles. Notice the variation in the amount of the meat, the expensive part of it. You see it ranges from 9 percent to 15⅔ percent.*

"THE CHAIRMAN. That is the percentage of meat?

"MR. CAMPBELL. Yes, you can see what this means to the consumer from the economic standpoint and also to the manufacturer who wants to maintain a definite standard. This shows exactly what competitive pressure will cause manufacturers to do. There is no way by which we can require a definite standard now. * * * "[4]

That the Congress was obviously impressed by this type of testimony and the exhibits displayed at the Committee hearings, is apparent from numerous statements in the various reports accompanying recommended bills[5] of which the following are typical—

" * * * The Government repeatedly has had difficulty in holding such articles as *commercial jams* and *preserves* and many other foods, to the time-honored standards employed by *housewives* and reputable manufacturers. The housewife makes preserves by *using equal parts of fruit* and sugar. The fruit is the *expensive* ingredient, and there has been a tendency on the part of some manufacturers to use *less and less fruit* and *more and more sugar.*

"*The Government has recently lost several cases where such stretching in fruit was involved because the Courts held that the well-established standard of the home, followed also by the great bulk of manufacturers, is not legally binding under existing law. By authorizing the establishment of definitions and standards of identity this bill meets the demands of legitimate industry and will effectively prevent the chiseling*

[4] *Ibid.*, pp. 1075-6.

[5] *Supra*, footnote 2.

operations of the small minority of manufacturers, will in many cases expand the market for agricultural products, particularly for fruits, and finally will insure fair dealing in the interest of the consumer."[6] (Emphasis ours.)

* * * * * *

"While the old law has been of incalculable benefit to American consumers, it contains serious *loopholes* and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions. *In considering the measure the committee had before it a host of exhibits and examples of abuses of the consumer's health and pocketbook, against which there is now no effective restriction or no restriction at all."*[7] (Emphasis ours)

It is respectfully submitted, therefore, that both the language of Section 401 and its legislative history raise the gravest doubts as to the correctness of the administrative construction of this Section.

The court below has expressly recognized the public importance of this fundamental question. It questions the propriety of our challenging the Administrator's jurisdiction since, in the lower court's view, this petitioner had waived the right to do so by appearing at the public hearing and requesting that its ingredient be specified as a permissive ingredient.[8] The significance of this is the fact that the lower court concluded that the importance of the question involved outweighed this supposed irregularity. It said in part—

"However, the issue before us is the validity and effect of an administrative regulation of nation-wide appli-

---

[6] H. Rep. No. 2139, 75th Cong., 2d Sess.; *Dunn, op. cit., supra,* p. 819.

[7] H. Rep. No. 2755, 74th Cong., 2d Sess.; *Dunn, op. cit., supra,* p. 552.

[8] This petitioner did not invoke, but rather submitted to the respondent's jurisdiction, but challenged it from the beginning; furthermore, it is elementary that jurisdictional and constitutional questions may be raised at any stage of a proceeding.

> cation to the food industry and of general importance to consumers. In the light of all of the interests involved we think possible inconsistencies in the position of the petitioner should not prevent us from considering and adjudicating * * *", this question. (Opinion p. 3).

In resolving this fundamental question against us, the court below relied almost altogether on statements contained in the opinion rendered by this Court in *Federal Security Administrator* v. *Quaker Oats Co.*, 1943, 318 U. S. 218. It also cited *Libby, McNeil and Libby* v. *United States*, 1945, 148 F. 2d 71, and *Land O'Lakes Creameries, Inc.*, v. *McNutt*, 1943, 132 F. 2nd, 653. However, the latter two cases themselves rest altogether on the language contained in this Court's opinion in the *Quaker Oats* case, at least to the extent to which they have any bearing on the questions here raised. Hence, for all practical purposes, the lower court rests its decision altogether on the *Quaker Oats* case.

By thus resting decision on the *Quaker Oats* case, the court below has raised the further important question of the meaning of that opinion. It is deemed important that this Court finally settle the question by precisely delineating the issues involved in the *Quaker Oats* case and restate precisely its holding therein. The reason for this suggestion is the fact that the *Quaker Oats* case is, in our opinion, one of the most widely misread cases of any we know. This stems from the fact that the opinion contains very broad statements which are meaningful and important determinations of fundamental questions when related to the issues before this Court for decision, but which lend themselves to distortion and misinterpretation when lifted out of context. This Court considered and so characterized one example of such misreading in the so-called "Imitation Jam" case (*62 Cases . . . Jam* v. *United States*, 340 U.S. 593, 71 S. Ct. 515 (1951)). It is important, therefore, that this Court finally decide whether the court below was correct in

concluding that the *Quaker Oats* case is decisive of the questions here raised, or whether, as we contend, these questions were not even before this Court in that case.

At the risk of appearing presumptious, but in the belief that this phase of our question will be clarified and underscored by our so doing, we shall undertake to analyze this Court's decision in the *Quaker Oats* case. As appears from the opinion in that case, the Administrator established standards of identity under the names "farina" and "enriched farina" respectively. The evidence before him on the issues raised by his proposal to fix and establish these standards, established certain basic facts, including: that a general dietary deficiency existed among a substantial portion of the consuming public in certain specified vitamins and minerals; that consumers preferred vitamin and mineral enriched foods; that there was no uniformity of commercial practice in enriching basic foods since most contained only one or the other of these substances; and that consumers were ignorant of the dietary values of these substances, hence were confused.

On the basis of this kind of factual background, the Administrator established a standard for "enriched farina" by fixing both the *kind* and the *levels* of vitamins and minerals which should be contained in any farina held out as having been nutritionally improved—"enriched." Vitamin D alone could not be added to farina since its presence would constitute the product a nutritionally improved farina—an "enriched farina"—which would fail to meet the standard for such a food in that it was lacking in the vitamins and minerals required to be present in a farina held out as nutritionally improved. Any label statement explaining the extent of departure from the standard would not serve to correct the legal defect resulting from the failure to meet the standard. This is in no way different in principle from fixing the kind and amount of fruit required in a fruit preserve, or the kind and quantity of constituents of any other food identified by a given name.

The validity of these regulations was successfully challenged before the United States Court of Appeals for the Seventh Circuit (*Quaker Oats Company* v. *Federal Security Administrator*, 129 F. 2d 76). The *assigned ground* for the attack on them was that the factual consideration as outlined above did not bear any relation to "honesty and fair dealing in the interest of consumers." The lower court accepted the Government's statement of the question as follows—

> "The real issue, of course, is whether the requirements of the regulation are reasonably related to the promotion of consumers' interests * * *." [129 F. 2d at p. 81]

It then continued, saying—

> "A study of the record leaves no room for doubt but that the hearing revolved largely around consumer interest as it related to health. In referring to the ingredients of enriched farina, it is stated in the respondent's brief: 'They are essential to the health and well being of our Nation.' In support of the regulations it is also suggested that they will prevent confusion among consumers as to their nutritional needs * * *. It is still further suggested that the regulations will promote consumer understanding of the relative value of enriched and natural foods." [129 F. 2d at p. 81]

After a detailed consideration of the statute, its legislative history, the findings and evidence relied upon, and acknowledgment that it could not substitute its judgment for that of the Agency, that court concluded—

> "The rule, however, is of no benefit to respondent in the instant situation because, as we have endeavored to show, the regulations, while purporting to be in the interest of consumers, do not promote honesty and fair dealing in their behalf. On this statutory requirement, essential to respondent's authority to act, the record is wholly deficient. In view of this situation,

> the action of respondent, in promulgating the regulations in controversy, was beyond his statutory authority. Such being the case, they must be set aside." [129 F. 2d at p. 83]

It should be noted that the health considerations in this order were to *promote* healthy diets in a field where dietary deficiencies existed, and not to make decisions of *food adulteration* by reason of possible health hazards resulting from an adulterated food.

It is apparent that decision in the lower court as to the Administrator's authority to promulgate the regulations under review, turned on the question whether the considerations of promotion of public health and minimizing of consumer confusion, as outlined above, bore any reasonable relation to promotion of "honesty and fair dealing in the interest of consumers." That court concluded they did not. This is important because this was the primary, if not sole, issue brought before the Supreme Court for review. This Court said—

> "Respondent [Quaker Oats Co.] challenges the validity of the regulations *on the grounds sustained below* and others so closely related to them as not to require separate consideration." (Emphasis added) [318 U. S. at page 224]

It seems clear to us that the questions now presented were *neither raised nor decided* by this Court in the *Quaker Oats* case. The court below disagrees. It seems to us of utmost importance that this issue be resolved by this Court.

II

It is also imperative that this Court consider and determine the constitutional questions raised.

As noted from reading it, Section 401 divides itself into two parts. The Administrator must first decide whether a standard should issue. This decision is required to rest on his judgment that promulgating a standard "will

promote honesty and fair dealing in the interest of consumers." Having thus decided that a standard should issue, he is enjoined by Congress to be "reasonable." That is all! This certainly is about as general as any delegation of legislative power could possibly be. The court below comes to the conclusion that this is sufficiently specific because of the inherent problems involved in food standardization, which do not lend themselves to a more specific statutory delineation. However, it is highly questionable whether this constitutes an adequate yardstick even when the statute is construed as we have proposed.

A reasonably good case can be made for a sufficiently specific delineation of legislative powers granted by this Section when its language is interpreted in the light of the statutory pattern of which it is a part, including Sections 402 and 406, and their legislative history. Such a construction, we contend, authorizes the respondent to fix the ingredients required to insure identity of a food and to fix their ratios in order to establish its standard of identity —its economic integrity—by insuring, for example, 45% of fruit in fruit preserves and 15% of chicken solids in chicken soup. However that may be, the court below has not even undertaken to consider the more specific question of constitutionality which we have raised, and which is inherent in the administrative construction of Section 401, namely, the power to fix and limit by a prescribed list, those ingredients which are *permissive*, but not *required* to insure a standard economic integrity; where the ultimate judgment of inclusion or exclusion of one or more of the listed ingredients is exercised, *not* by the Administrator but by the *food processor*. It seems to us that if Section 401 does in fact authorize such administrative action, this would indeed be a case of "delegation running riot." It would constitute a delegation of administrative powers with the power of *sub-delegation* of some of the functions to the food processor. We respectfully submit that a question of such fundamental implications should be resolved by this Court.

III

Our third question, too, raises a fundamental issue of vital importance to the whole regulated food industry. As pointed out, the administrative action excluding this petitioner's ingredient from the bakery products standardized, involves two basic factual questions, namely, whether this ingredient *may be dangerous to health* and whether the characteristics imparted to bread by its presence therein *make that bread appear better or of greater value than it is*. However, if either of these questions is answerable in the affirmative then our ingredient is already outlawed by operation of law, since bread containing an ingredient possessing such properties, has been proscribed by Congress in enacting Sections 402(a) and (b) of the Act. Congress has left no room for administrative discretion in this matter since it has already declared foods containing such ingredients to be outlaws of commerce. It has only enjoined the Administrator to enforce these provisions of the law when he believes these to be the facts.

Congress has also prescribed the means of enforcement by authorizing seizure of the food so adulterated, enjoining manufacturers from shipping such adulterated foods, and criminal prosecution of the shipper in interstate commerce of such adulterated foods. Inherent in these proceedings is the requirement that the Government establish the affirmative of the issues of fact of alleged adulteration, by a preponderance of evidence in civil proceedings and beyond a reasonable doubt in criminal proceedings, to the satisfaction of a judge or jury. This petitioner contends that the Administrator may not deprive it, or any food manufacturer, of these rights and place it in a position of having to establish the *negative* of those issues to *his* satisfaction, merely by electing to hold a food standard hearing. The viscousness from the standpoint of a regulated manufacturer of such a construction is best illustrated by the case at bar. The respondent has, himself, found as a fact that

there is no evidence of injury to health from the consumption of bread over a life span containing our ingredient in the quantity specified. He has, therefore, expressly given us the reason why he did not undertake to enforce the applicable statute, namely, that there is no available evidence recorded *anywhere,* including upwards of 10,000 pages of transcribed testimony on the issues, to establish the proof required of the Government to establish likely health hazard. He, therefore, held his hearing and now insists that we have failed to establish the *negative* of this issue to *his* satisfaction.

The court below disposes of this vital question by relying on cases in two of which the factual background provided a basis for raising this question, but where it was neither raised nor decided. We have already shown that this question was not involved in the *Quaker Oats* case, the principal case relied on also on this issue, and could not even have been raised since no questions of adulteration were there involved. We happen to know that in *Libby, McNeil and Libby* v. *United States,* 1945, 148 F. 2d 71, another of the three cases relied on, the questions here raised were intentionally omitted because it was desired to restrict argument to the question of whether a wholesome food *truthfully labeled* could constitutionally be denied the channels of interstate commerce. That court stated this as the question before it for decision. Nor was the question raised or decided in *Land O'Lakes Creameries, Inc.* v. *McNutt,* 1943, 132 F. 2d 653, the only other case cited. There the attack on that regulation was not by the regulated industry, which could not have raised our question because no such issue was resolved against it, but by a competitor in no wise restricted by that regulation. The competitor contended that the regulation fixing a standard for oleomargarine was invalid because it provided a basis for practicing unfair methods of competition in that it authorized misbranding and adulteration of margarine in violation of Sections

402(b) and 403(c) of the Act. It was held that the challenged regulation was not invalid on this ground.

The question here raised is novel and of great importance. It may not be brushed aside lightly by the suggestion, as the court below has suggested, that our reasoning "lends itself to the *reductio ad absurdum* type of refutation." The court suggests that "logically petitioner would not let the Administrator challenge even the addition of a bit of arsenic to bread as inconsistent with any proper standard of identity or subject to control under the procedure for food standardization prescribed in Section 401." (Opinion page 5) The court is quite correct in its interpretation of our contention. However, unfortunately it has not seen fit to reply to the answer which we gave to this very question on oral argument. We continued by saying that we by no means meant to imply that he should not concern himself with questions of the presence of arsenic in bread. We suggested that, on the contrary, this should become his primary concern and that he should afford the consumer the best and most expeditious protection provided by Congress, namely, prompt enforcement of Section 402—seizure, injunction, criminal prosecution. Consumers' interests would indeed be poorly served if reliance were placed on the promulgation of standards under Section 401 to protect him against arsenic in bread.

We submit that, at best, a grave question exists as to whether the regulated industry may be deprived of the important rights which it has under those provisions of the law specifically calculated to protect consumers against the specified health hazards and deceptions, by a statutory interpretation resting on inferences drawn from unusually general language. We suggest that this Court's holding in *Youngstown Sheet and Tube Co.*, et al. v. *Sawyer*, 343 U. S. 579, 72 S. Ct. 863 (1952), is applicable here, and particularly applicable is the following statement included in Mr. Justice Frankfurter's concurring opinion in that case—

> *"It is one thing to draw an intention of Congress from general language and to say that Congress would have explicitly written what is inferred, where Congress has not addressed itself to a specific situation. It is quite impossible, however, when Congress did specifically address itself to a problem, as Congress did to that of seizure, to find secreted in the interstices of legislation the very grant of power which Congress consciously withheld.* To find authority so explicitly withheld is not merely to disregard in a particular instance the clear will of Congress. It is to disrespect the whole legislative process and the constitutional division of authority between President and Congress." (Italics ours)

IV.

A final question which, in our judgment, requires consideration by this Court is the question raised by this petitioner in challenging the legality of the respondent's stated grounds for the exclusion of this petitioner's ingredient. As noted, the respondent finds affirmatively that there is no ~~likelihood~~ evidence of injury from bread containing this ~~tioner's~~ ingredient as proposed, but he nevertheless excludes it on the ground that "the results of the pharmacological tests reported do not warrant the conclusion that there is no likelihood of injury from bread containing these substances in the amounts proposed * * *." (Finding 42). The respondent noted as part of his findings that substances, including polyoxyethylene monostearate, were proposed as ingredients for salad dressing in 1947 and that his final order in that proceeding excluded them and "pointed out among other things that these compounds had not been adequately tested to determine their safety." (Finding 41). Since the evidence presented to him in 1947 was thus characterized by him, a mass of additional evidence was presented on these issues in the instant hearing, upwards of 10,000 pages of transcript of testimony. Yet, the worst he can find is that there is *no* evidence of injury, but that the tests are not enough. It has been said that

negative findings serve as an escape hatch for indecision. Here is indeed a good example.

This petitioner contends that the respondent's findings do not establish a valid basis for denying its product as an ingredient in bread on the ground of insufficiency of pharmacological tests, unless the finding of inadequacy is related to a specific standard of adequacy, spelled out specifically by affirmative findings of fact based on the record. The food industry is entitled to a definite yardstick whereby it may determine *sufficiency*, in the presence of a finding of *insufficiency*.

CONCLUSION

For the foregoing reasons this petition for a writ of certiorari should be granted.

Respectfully submitted,

MICHAEL F. MARKEL,
Counsel for Petitioner

Of Counsel:

WAYNE K. HILL

No. 610

IN THE

United States Court of Appeals

FOR THE THIRD CIRCUIT

Case No. 10765

ATLAS POWDER COMPANY, a Corporation, *Petitioner,*

v.

OSCAR R. EWING, Federal Security Administrator, *Respondent.*

PETITION FOR REVIEW OF AN ORDER OF THE FEDERAL SECURITY ADMINISTRATOR

REPLY BRIEF FOR PETITIONER

OSCAR COX
1210 18th Street, N. W.
Washington 6, D. C.
Attorney for Petitioner

C. C. GAMMONS,
KENNETH E. MULFORD,
ROGER R. HORTON,
Delaware Trust Co. Bldg.,
Wilmington, Delaware.
LLOYD N. CUTLER,
LOUIS F. OBERDORFER,
HERBERT L. PACKER,
DONALD F. TURNER,
1210 18th Street, N. W.,
Washington 6, D. C.,
Of Counsel.

TABLE OF CONTENTS

PAGE

INTRODUCTION 1

POINT I—

The Administrator's order is obviously and materially ambiguous and should be remanded if the Court finds that the Administrator erred on either of the two grounds which he stated for excluding our products from bread 6

POINT II—

The Administrator's finding that the Atlas products are deceptive while the competing products are non-deceptive is not supported by substantial evidence and is illegally discriminatory.. 8

POINT III—

The Administrator has no statutory power to exclude a proposed ingredient as to which he finds there is no definite evidence of injury, on the ground that its proponent has failed to prove that there is "no likelihood of injury" to persons consuming the ingredient over a life span 13

POINT IV—

The Administrator has failed to justify his discrimination between our products and the competing products on the issue of safety 16

PAGE

POINT V—

The hearing should be reopened to consider the laboratory experiments on the safety of our products which the Food and Drug Administration has been conducting since 1948 22

CONCLUSION 26

APPENDIX

Correspondence between counsel for Atlas Powder Company and counsel for the Administrator with respect to laboratory experiments on the safety of the Atlas products conducted by the Food and Drug Administration 1a

AUTHORITIES CITED

CASES: PAGE

Cream Wipt Food Products Co. v. *Federal Security Administrator,* 187 F. 2d 789 ..... 11, 12

Federal Security Administrator v. *Quaker Oats Co.,* 318 U. S. 218, 63 S. Ct. 589 (1943) 14

Fogarty v. *United States,* 340 U. S. 8, 71 S. Ct. 5 (1950) 15

Holloway v. *Dunham,* 170 U. S. 615, 18 S. Ct. 784 (1898) 7

Interstate Commerce Commission v. *Jersey City,* 322 U. S. 503, 64 S. Ct. 1129 (1944) 28

National Labor Relations Board v. *Jarka Corp.,* No. 10715 (C. A. 3, August 15, 1952) 7

United States v. *United Mine Workers,* 330 U. S. 258, 67 S. Ct. 677 (1947) 15

STATUTES, ETC.:

Federal Food, Drug and Cosmetic Act, 52 Stat. 1040 *et seq.,* 21 U. S. C. A. § 301, *et seq.*

Section 401 13

402(a)(1) 14

402(a)(2) 14

701(f)(2) 26, 27, 28

H. R. Rep. No. 3254, 81st Cong., 2d Sess. 10 (1951) 15

MISCELLANEOUS:

Crawford, *The Food and Drug Administration's Viewpoint on Chemicals in Foods,* 7 Food Drug Cosmetic Law Journal 85 (1952) 18

Annual Report of the Federal Security Agency, Food and Drug Administration 17 (1951) 25

INTRODUCTION

Our three principal comments on the Administrator's Brief are:

(1) It does not focus on the precise form of relief for which we pray.

(2) It tries to cover the inadequacy of the Administrator's safety findings to support the exclusion of our products by interpreting the evidence in ways which are not corroborated by the findings themselves.

(3) It fails to advance any convincing reason justifying the Administrator's plain discrimination against the Atlas products, in favor of the competing classes of surface-active agents.

First. As regards relief, we do not ask this Court to "weigh the evidence, rewrite the findings and reach an independent expert conclusion on a mass of scientific evidence." (Compare *Administrator's Brief, p. 36*). We do not ask this Court to invade the areas of the Administrator's special competence. What we do ask is that this Court exercise its specific statutory authority to reverse and to remand the Administrator's findings and order, and to direct a reopening of the hearing which the Administrator closed more than three years ago, 32 months before he entered his final order.

We are entitled to a remand because, on the record as it stands, the Administrator's findings and order, so far as they affect the use of Atlas products in bread, are ambiguous, unsupported by substantial evidence, illegally discriminatory and in excess of the power granted to him by Congress.

We are entitled to a reopened hearing, upon remand, to consider additional material evidence about the safety of all surface-active agents, including the tests conducted by the Food and Drug Administration itself, and to consider the additional evidence which conclusively demonstrates that the competing classes of surface-active agents cannot properly be found non-deceptive at normal levels of use unless a similar finding of non-deception is made for the Atlas products.

Second. The Administrator's Brief makes a bogey man attempt to communicate the idea that our products are "poison." By contrast, his plain *finding* is that (on the basis of the evidence adduced at the hearings which closed more than three years ago) "the record shows no definite evidence of injury from the use" of the Atlas products "in amounts in which they are likely to occur in the diet from their use in bread." *A. 473.* In those hearings there was no clinical or any other evidence that a single human being had suffered any injury at all from the use of the Atlas products, although they had been used in billions of loaves of bread consumed by millions of people. Tests on human beings conducted on the Atlas products by competent medical men such as Dr. Perry Culver of the Massachusetts General Hospital and the Harvard Medical School, and introduced in the hearings, showed no evidence of any injury

and no evidence of any acute or chronic toxicity. *A. 470-1.* In all of the animal feeding tests conducted on the Atlas products not only by Atlas-sponsored scientists, but also by scientists sponsored by our competitors who were obviously trying to keep the Atlas products out of bread, there was no basis on which the Administrator could find that there was or might be evidence of injury from their use in the amounts likely to be consumed in bread, and he did not so find. *A. 469, 472.* Despite the fact that counsel for the Administrator in his Brief now attempts to stretch the evidence and treat it in such a way as to make new findings, and to imply that the Administrator found that our products are not safe, the fact is that the Administrator himself found no evidence of injury from the use of Atlas products in the amounts likely to be consumed in bread, and he did not find that the Atlas products would or might cause injury. *A. 472-3.*

The Administrator, although he found no evidence of injury from the use of the Atlas products and did not find them unsafe, nevertheless proceeded to hold that Atlas had failed to meet a virtually absolute negative test set up by him for the first time in the administration of the Act. He said that "the results of the pharmacological tests reported do not warrant the conclusion that there is no likelihood of injury from bread containing these substances in the amount proposed to persons consuming it continuously over a life span." *A. 473.* This negative finding is not the equivalent of an affirmative finding that our products are unsafe. Such an affirmative finding is the only lawful foundation for a decision to exclude our products from bread on the ground of safety. The unsupported arguments in the Ad-

ministrator's Brief are not effective substitutes for a lawful finding.

Third. The illegal discrimination which the Administrator has practiced appears from the face of his own findings in support of this order. The efforts of his counsel to amend the findings in this respect are unsuccessful. The Administrator's findings, order and memorandum opinion considered three types of products—the Atlas product (Myrj 45), the Swift and Co. product (mono- and diglycerides) and the Hachmeister Co. product (diacetyl tartaric acid esters). With respect to all three products the Administrator found that:

(1) They have the capacity to make bread feel soft and, therefore, deceptive to consumers.

(2) They are all "surface-active" agents.

(3) Surface-activity, common to them all, raise a common question as to their safety.

(4) No final judgment could, at that time, be made about the safety of any of the three products for use over the life span.

The Administrator illegally discriminated because, having found all three products to be identical in four crucial respects, he decided to admit two surface-active agents (mono- and diglycerides and diacetyl tartaric acid esters) into the bread standard at restricted levels pending a reopened hearing as to their safety, and to exclude the Atlas products at any level. He refused to reopen the record to

consider evidence as to our products, or to admit us temporarily pending a reopening hearing.

The crowning example of discrimination is the Administrator's action with respect to diacetyl tartaric acid esters. In the Administrator's tentative order he excluded the diacetyl product on substantially the same safety grounds as he excluded our products. *A. 8.* In his final order, he admitted the diacetyl product to the standard by taking account of evidence admittedly outside the record presented to him after the hearings ended. *A. 463.* At the same time he refused to admit our products and refused to consider additional evidence accumulated after the close of the hearings.

We do not say that the Administrator made a mistake in admitting those products to the standard although the last word has not yet been said as to their safety, as indeed the last word has not yet been said on many other useful items long accepted as ingredients of our diet. His mistake was in ruling our products out, while admitting the competing products, with no substantial basis, in or out of the record, for this discrimination, which closes down our business and forfeits our market to our competitors.

In this Reply Brief we shall demonstrate the failure of the Administrator's Brief to repair his case on any of the crucial issues in this proceeding.

POINT I.

The Administrator's order is obviously and materially ambiguous and should be remanded if the Court finds that the Administrator erred on either of the two grounds which he stated for excluding our products from bread.

The Administrator's Brief now takes the position that his findings on safety and deception were independent grounds for the exclusion of our products, and that the ultimate finding must stand if he was right on either of these grounds regardless of any error he committed on the other. *Administrator's Brief, p. 33.*

This position is inconsistent not only with the plain language of the findings, but also with the Administrator's action, taken concurrently with the issuance of his order, in denying our Motion to Reopen. At that time he stated that he might reconsider the question of a reopening after we "completed" the experimental work on the *safety* of our products. *A. 483-4.* In a letter dated May 12, 1952, he advised Atlas that he did not "believe that Atlas type products should be permitted to be used in bread *pending* the completion of further investigational work." *A. 457.* (Emphasis added.)

The plain implication of what the Administrator said is that he might be willing to alter his ultimate conclusion about the suitability of our materials on the basis of a further showing as to their safety. Obviously, if the Administrator meant that the ground of deception was of itself sufficient to exclude our products, his invitation to carry out further expensive and time-consuming studies on safety was a trap rather than the helpful suggestion ostensibly intended. It is more likely that the Administator's invitation meant what it said.

Similarly, if the Administrator had not erred in finding that the Atlas products deceive, the Administrator's findings indicate that he might have approved at least the temporary use of the Atlas products, despite his doubts as to the sufficiency of the proof as to their safety. Once the Administrator had determined that the mono- and diglycerides and the diacetyl tartaric acid esters did not deceive, he decided to permit their temporary use notwithstanding his specific finding that the safety of these materials over the life span had not yet been proved. With the findings in their present ambiguous state, this Court cannot tell whether or not the Administrator would have reached the same decision as to the Atlas products, if he had not erroneously found that the Atlas products deceive.

As we have shown in our main brief (pp. 15-18), it follows that if either of the two stated interdependent grounds for the exclusion of our products is erroneous, this Court must reverse and remand the case for further hearings. In an attempt to avoid this necessary conclusion, the Administrator has cited several decisions. Two of these decisions may fairly be cited for the proposition that where a finding is made on two grounds, *either* of which is sufficient to support the finding, it does not matter that one ground is wrong.* But reliance on those cases begs the question presented here, which is whether a decision based on two grounds can be sustained when one ground is wrong and when the record indicates that the Administrator might have arrived at a different result if the error had not been made.

**National Labor Relations Board* v. *Jarka Corp.*, No. 10715, (C. A. 3, August 15, 1952); *Holloway* v. *Dunham*, 170 U. S. 615, 618 (1898). The Administrator also cites in a footnote two additional decisions whose relevance to this question is not apparent to us. *Administrator's Brief, p. 35, n. 44.*

POINT II.

The Administrator's finding that the Atlas Products are deceptive while the competing products are non-deceptive is not supported by substantial evidence and is illegally discriminatory.

The Administrator's discrimination between our products and the mono- and diglycerides on the issue of deception is unsupportable. He first suggests that there is a basis for treating them differently because the mono- and diglycerides perform functions in bread which our products do not perform.* The Administrator does not dispute that both classes of products retard staling and prolong softness; and it is this common characteristic—not others which they may not share—that gives rise to the charge of deception. It is also this common characteristic which brings the two classes of products into economic competition, and which explains the intensive efforts of Swift & Co. at the bread hearings to bring about the exclusion of the Atlas products from bread.

There is, of course, a basic question, which the Administrator has nowhere answered, whether our products or the competing products deceive consumers any more than

*The evidence of record showed that Myrj 45 not only makes bread feel softer in the grocery store, but also causes the bread to stay softer and fresher for a longer period of time after the wrapper is opened and use begins, retaining palatability even though consumption is spread over a period of several days. *A. 2828, 2878, 2881.* The evidence of record also showed that Myrj 45 improves the machining and handling qualities of the bread dough and the texture of the finished product. *A. 736.* While these functions are not identical to the functions of the mono- and diglycerides, they are very similar, and they are important and useful functions entirely apart from the function (shared by the mono- and diglycerides) of making the bread feel softer on the grocery shelf.

do the air-tight cellophane wrappers, which also keep bread softer for a longer period. However that may be, the Administrator does not seriously dispute that the charge of deception, if applicable at all, is applicable to both classes of products. Instead, he tries to justify the result by picking a level—20% of the shortening content of bread—at which he says the mono- and diglycerides do not deceive. He now admits that the only basis in a 17,000 page record for this finding is the testimony of Dr. Bradley. *Administrator's Brief, pp. 63-64.*

In our main brief (pp. 23-26) we showed that Dr. Bradley's testimony on this point was based on his erroneous recollection that certain "high ratio" shortenings mentioned at the 1941 hearings contained 20% mono- and diglycerides. As a matter of fact, "high ratio" shortenings contained from 4 to 10% mono- and diglycerides. When confronted with this fact, Dr. Bradley not only admitted that his recollection, and therefore his 20% figure, was wrong. He specifically stated that he had *no* basis on which to set an upper limit on the use of mono- and diglycerides.

The Administrator's only reply is to point out an earlier Bradley reference to a 20% level. Both references occurred on the same day. A fair reading of Bradley's entire testimony shows that *both* his references to a 20% level were based on his erroneous recollection of the mono- and diglyceride content of "high ratio" shortenings. *A. 693-4, 706.* And whatever the basis for Dr. Bradley's mention of the 20% figure, he completely retracted his testimony. On the very next day he admitted not once, but twice, that he had had no basis at all on which to set an upper limit for the use of mono- and diglycerides.

The first admission came in answer to questions by counsel for Atlas:

> "Q. In that answer on 5857, you refer to statements which you made earlier concerning these shortenings and you seem to be basing some of your opinions on those shortenings.
>
> "It is not clear to me, and I wonder if you would clarify a bit what type of answers were there in the record when you were referring to these high ratio shortenings in your own mind as basing your answers on. A. My memory of the testimony which had been introduced at the bread standards hearings in 1941 in regard to high ratio shortenings was that evidence had been introduced at that time that high ratio shortenings contained as much as 20 per cent mono- and diglycerides. I had not had time to reread the testimony presented then, but I have been assured by people who should be familiar, more familiar with that testimony than I am, that my impression is erroneous, and that the evidence presented at that time did not indicate that as much as 20 per cent mono- and diglycerides were incorporated in high ratio shortening.
>
> "Q. Well, now, Dr. Bradley, if the prior record referred to such shortenings as containing from 4 to 10 per cent mono- and diglycerides, and that had been your impression *yesterday,* would you have revised then any answers that you gave *yesterday?* A. *I think that the upper limit of the mono- and diglycerides permitted in shortening for use by the bread baker should be determined from experimental evidence, which I am not prepared to present,* and that that upper limit should be determined on the basis of the qualities produced in the finished loaf of bread by shortenings containing various percentages of mono- and diglycerides, when used in the

manner employed by the baker." *A. 707-708.* (Emphasis supplied.)

And in answer to questions by counsel for the Administrator, Dr. Bradley confirmed the admission that his evidence was not probative on the issue of an upper limit for mono- and diglycerides:

> "Q. Concerning the level of monoglyceride in bread shortening, do I understand from your answer to Mr. Mulford that *you do not have enough information to set a hypothetical limit on the amount of mono- and diglycerides desirable in bread shortening? A. Yes, sir, your understanding is correct.*
>
> "Q. Have you made an exacting study of the subject using various monoglycerides combined with various types of triglycerides? A. No, sir.
>
> "Q. Since the standard we are setting includes rolls and buns, do you believe any possible answer should include these products? A. Yes, sir.
>
> "Q In arriving at the answer to this question, do you consider that practical field experience had by operating commercial bakers is important? A. Yes, sir." *A. 708-709.* (Emphasis supplied.)

The "practical field experience by operating commercial bakers" which Dr. Bradley suggested as the proper basis for setting a limit on the use of mono- and diglycerides is not cited by the Administrator and, so far as this record shows, does not exist.

This Court has recently set aside a deception finding made by the Administrator where the sole basis for the finding was the testimony of a witness who had an inadequate foundation for his conclusion. *Cream Wipt Food Products Co.* v. *Federal Security Administrator,* 182 F. 2d

789, 791 (C. A. 3, 1951). Here the Administrator has made a deception finding on the sole basis of testimony which was completely retracted by the witness who gave it.

We have also pointed out that the 20% level is meaningless, since it is tied to a variable—the shortening content of bread. The Administrator suggests that his finding is meaningful in terms of a median level of shortening *Administrator's Brief, p. 65.* But the Administrator did not prescribe a median level of shortening. Any amount is permissible under the terms of his order.* *A. 475.* The basic difficulty is that the hearings did not focus on what the Administrator has since conceived to be the important question of a level of use in terms of "deception". If the issue is important, it deserves more careful treatment in a reopened hearing.

We do not understand the Administrator to say that there is no level at which our products are non-deceptive. He is content with the assertion that the record shows no such level. *Administrator's Brief, p. 62, n. 74.* A similar absence of evidence did not prevent him from finding a non-deceptive level for pure monoglycerides, *A. 461,* and from prescribing such a level for diacetyl tartaric acid esters without bothering to make a finding. *A. 475.* Here again, the Administrator's difficulty arises because the hearings were not guided in conformity with his afterthought that a line can be drawn between deceptive and non-deceptive levels of use.

The Administrator attempts to slough off our additional evidence on the deception issue by picking what he conceives to be flaws in the testing methods. If cross-examination of those methods is necessary, the place for it, we would suggest, is the reopened hearing to which we are entitled.

---

*Thus bread containing 3% of shortening would include .6% of mono- and diglycerides; bread containing 6% of shortening would include 1.2% mono- and diglyceride.

POINT III.

The Administrator has no statutory power to exclude a proposed ingredient as to which he finds there is no definite evidence of injury, on the ground that its proponent has failed to prove that there is "no likelihood of injury" to persons consuming the ingredient over a life span.

In our main Brief (pp. 35-39) we analyzed the specific language, context and legislative history of the food standard provisions of the Food, Drug and Cosmetic Act under which the Administrator acted to bar our products from bread. Section 401. From this analysis we reached the conclusion, and urged it to this Court, that Congress has not authorized the Administrator in food standards proceedings, or otherwise, to exercise the power under which he purports to act here: *i. e.*, the power to exclude from food an ingredient about which there is no definite evidence of injury because its harmlessness when consumed by human beings over a life span has not been conclusively established.

The Administrator purports to restate our argument on this point, but misstates it for purposes of his reply. His counsel has told the Court that we are arguing that "the Administrator cannot take action to exclude a suspect chemical unless the proof shows definite past injury from it." *Administrator's Brief, p. 28.* He then proceeds to argue (as we would agree) that the Administrator does not have to find actual past injury.

What we urged in Point III of our main Brief is that the Administrator's power to exclude an ingredient from a food standard on the ground of safety is no greater than

his statutory power, under the sections concerned specifically with health, to bar that material from the market by injunctive or criminal action. The Administrator is authorized to seize, enjoin the sale of, and prosecute the purveyor of adulterated food. In such a proceeding, it would not be necessary for the Administrator to prove "definite past injury". *Administrator's Brief, p. 28.* It would be necessary only for him to carry his burden of proving either that [redacted] our product was a poisonous or deleterious substance which "may" render bread injurious to health or that our product was a poisonous or deleterious *addition* to bread. Sections 402(a)(1) and (2). So in this food standard proceeding, we contend that an order excluding that ingredient must be based on a minimum *affirmative* finding either that our product *is* poisonous or deleterious and *may* render bread injurious to health, or that it *is* a poisonous or deleterious additive.

The Administrator has made no such finding here.

Even in the *Quaker Oats* case, quoted at length in the Administrator's Brief in this case, the Administrator found *affirmatively* that use of the proponent's products "*would* tend to confuse and mislead consumers." *Federal Security Administrator* v. *Quaker Oats Co.,* 318 U. S. 218, 220 (1942). (Emphasis supplied.) That case did not approve exclusion from a food standard based on a *negative* finding that the proponent had failed to prove that there was no likelihood that its product would confuse and mislead consumers. It is our contention that exclusion on the basis of such a finding would be illegal and unauthorized, not only on the issue of deception but also on the issue of safety.

Here the Administrator has excluded our product on the completely negative, question-begging finding that, while

there was no "definite evidence of injury . . . the results of the pharmacological tests reported do not warrant the conclusion that there is no likelihood of injury from bread containing these substances in the amount proposed to persons consuming it continuously over a life span." (Emphasis supplied.) He did not find that our product is poisonous or deleterious and may be injurious to health. He did not find that our product is a poisonous or deleterious additive.

The statute does not authorize the exclusion of an ingredient from a food standard on the basis of the negative finding which the Administrator has made. Nor has the Administrator been able to buttress his novel contention with apt reference to legislative history or to a decided case.*

---

*In an attempt to supply authority where none exists, the Administrator cites the report of the Select Committee of the House of Representatives, which recently investigated the use of chemicals in foods. H. R. Rep. No. 3254, 81st Cong., 2d Sess. 10 (1951). *Administrator's Brief, p. 28.* Whatever support this Committee opinion might give to an order of the Administrator excluding a food which he determines *may* injure health, the quotation from the Committee opinion does not support an order based on a negative finding that Atlas has failed to prove that there is no likelihood of harm from consumption of its products over a life span. It may also be noted that the Supreme Court has repeatedly refused to accept the opinion of members of a subsequent Congress about legislation enacted by a previous Congress "as authoritative guides to the construction of" that legislation. *United States* v. *United Mine Workers,* 330 U. S. 258, 281-282 (1947); *Fogarty* v. *United States,* 340 U. S. 8, 13-14 (1950). This ruling is especially applicable to a case like the present one where no member of the Committee expressing the opinion was a member either of the Committee which drafted the legislation or of the Congress which enacted it.

POINT IV.

The Administrator has failed to justify his discrimination between our products and the competing products on the issue of safety.

In our main Brief, we pointed out that even if the Administrator possesses the power whose existence we question, his decision to exclude our products while admitting the products of our competitors constitutes a discrimination unsupported by substantial evidence (pp. 40-61). The crucial part of the Administrator's Brief is not the nineteen pages (pp. 35-54) in which he argues that each of his specific findings as to our products is supported by substantial evidence,* but the five pages (pp. 54-58) in which he argues that the *discrimination* between our products and the competing products is supported by substantial evidence.

On page 55 of his Brief, the Administrator attempts to rationalize the distinction drawn. This rationalization consists of four points as to which the Administrator contrasts our principal product sold for use in bread—Myrj 45—with the competing mono- and diglycerides, to the detriment of our product. Each of these distinctions is unsubstantial, as we show below:

A. Period of Use

The Administrator suggests as one ground for the distinction that the mono- and diglycerides have been used in foods for 20 years while our product has only been used since 1947. Actually, the mono- and diglycerides at the

*There is no need to repeat here the answers to that contention made in our main Brief (pp. 40-61).

levels presently permitted have not been in bread for any longer than our product. Their widespread use in bread coincides closely with ours. In any event, continued use for 10 years or for 20 years does not resolve the issue of the cumulative effect of a substance over the life span.

The Administrator attempts to extend the time distinction to include diacetyl tartaric acid esters. He makes the evasive statement that "all of the ingredients in it have been used in food for some time." *Administrator's Brief, p. 57.* The ingredients and the resulting chemical compounds are two entirely different things. The very citation relied on to support this basically irrelevant statement shows that diacetyl tartaric acid esters were developed on a research basis beginning only in 1947 and have a shorter and far less widespread use in the food supply than do our products. *A. 3090-3092.*

B. *"Natural"* v. *"Chemical"* Substances

Another difference relied upon by the Administrator is the assertion that mono- and diglycerides are "closely related" to natural fats while our products are chemicals "closely related" to known poisons. The fact is that mono- and diglycerides are not natural fats, but at best decomposition products of natural fats, while diacetyl tartaric acid esters have no analogue at all in nature. *Tr. p. 11101; A. 431.* Moreover, whether a particular food or chemical substance is "closely related" to another food or chemical substance, as the Administrator's Brief uses that expression, is meaningless in terms of safety; for example, grain alcohol (ethyl alcohol) is "closely related" to wood alcohol (methyl alcohol); glycerol monolaurate (a type of mono- and diglyceride excluded by the Administrator from this very bread

standard) is "closely related" to glycerol monostearate and the rest of the mono- and diglycerides (which are admitted). Furthermore, both our products and the competing products are produced by chemical processes. As a representative of one of the manufacturers has testified, the mono- and diglycerides are produced commercially by chemical reactions in a tank. *A. 115-116.* In the face of this fact, the notion that the Administrator need not inquire into the safety of the mono- and diglycerides because they are "natural" is not a *substantial* basis for the discrimination practiced here.*

The other branch of the Administrator's argument on the "chemical-natural" dichotomy is a contention that polyoxyethylene monostearate "contains residues of poisonous impurities." In our original Brief we showed that even if there were any quantity of ethylene glycol present in Myrj 45, it would amount at most to four parts per million in a loaf of bread. *A. 1970.* We pointed out that if a person ate a whole loaf of bread daily, he would take in less than 0.0009 grams or less than 3/100,000ths of an ounce each day. And the fact remains that there was not even a contention that such a small amount of ethylene glycol could be acutely toxic. Moreover, there can be no question of chronic toxicity. The two characteristic *chronic,* toxic effects from the consumption of harmful amounts of

---

*The Commissioner of Food and Drugs agrees that the distinction is not substantial. "Much confusion has come from the convenient but inaccurate . . . expression 'chemicals in food.' The ineptness of that expression is apparent when we consider that foods themselves are chemicals, and that the living organism which consumes food is itself a complex of chemicals in which uncounted chemical reactions sustained by foods are continuously occurring." Crawford, *The Food and Drug Administration's Viewpoint on Chemicals in Foods.* 7 Food, Drug, Cosmetic Law Journal 85 (1952).

ethylene glycol are (1) excretion of oxalic acid and (2) kidney damage. Neither of these effects has appeared from feeding Myrj 45 to animals.*

C. Metabolic Fate

The Administrator suggests as a third basis for distinction that the mono- and diglycerides are metabolized in the body in the same manner as natural fats, while the metabolic fate of the polyol portion of Myrj 45 is "unknown". Again, the Administrator's counsel says more than the Administrator felt that the evidence permitted him to say. There is not one word in the Administrator's findings to suggest that the metabolic fate of mono- and diglycerides is known. He does, however, suggest that their metabolic fate is known in his memorandum opinion. *A. 479.* But when one examines the few casual references in the record to the metabolic fate of the mono- and diglycerides, it is obvious why the Administrator elected not to make a finding on that issue. *A. 603-606.* Furthermore, the Food Protection Committee of the National Research Council has specifically mentioned the metabolic fate of the mono- and diglycerides as a problem which remains to be answered before a final judgment on their safety can be made. *A. 381.* We submit that it is improper for the Administrator to attempt to use as a basis for distinguishing between our products and the mono- and diglycerides a purported fact which he himself has failed to find, and a question which has been raised with respect both to our products and the competing products.

---

*The Administrator's Brief suggests that eating Myrj 45 caused increases in the oxalic acid content of human urine. This is not apparent from the record references cited by the Administrator, and, as set forth at p. 55 of our main Brief, is negatived by Finding 41. *A. 471.*

Equally untenable is the other branch of the Administrator's argument—the statement of his counsel that the metabolic fate of the polyol portion of Myrj 45 is "unknown". That statement is presumably a paraphrase of the Administrator's memorandum opinion. Yet examination of his memorandum opinion shows no reference at all to the metabolic fate of Myrj 45. *A. 478-484.* And his actual finding on the issue falls far short of the argument now being made. *A. 470.*

D. Proof of Safety

In conclusion, the Administrator's Brief states another ground for discrimination that again goes far beyond his findings or even his memorandum opinion. He says, "on the record, the products [mono- and diglycerides] are safe and no question was raised regarding their safety." "On the record" or "off the record," it is hard to reconcile this statement with the Administrator's admission that the safety of the mono- and diglycerides has yet to be established. *A. 459, 468.* There are two answers to the assertion that no question was raised regarding the safety of the mono- and diglycerides. First, this statement ignores the testimony of Dr. Harrisson and the work done by Braun and Shrewsbury, which showed damage from the feeding of mono- and diglycerides at high levels. *Atlas Brief, p. 51; A. 3216; Exh. 370; Exh. 378.* Second, the Administrator's assertion that no question was raised begs the very question presented by this review proceeding—whether, on this record, the Administrator had the *duty* to raise questions regarding the safety of the mono- and diglycerides once he chose to raise questions about the safety of the Atlas products. In any event, the same questions were authori-

tatively raised about *both* classes of products by the National Research Council *before* the promulgation of the final order in this proceeding. *A. 379-381.* Proponents of mono- and diglycerides and others have admitted before a Congressional Committee that the requisite safety studies have not been conducted. *A. 116-123.* It is consequently improper to include the mono- and diglycerides while excluding our products.

In stating the other side of this final comparison, the Administrator's counsel again goes beyond what the Administrator found and what the record supports when he states that "there are grave doubts" about the safety of our product. If the Administrator had "grave doubts" about the safety of Myrj 45, he did not say so in his findings. His counsel's afterthought that "grave doubts" would be a good argument to raise can hardly contradict the Administrator's considered finding on the record that "the record shows no definite evidence of injury" from the use of our products. It is a far cry from "grave doubts" to the cautiously worded finding that Atlas has not managed to convince the Administrator that "there is no likelihood of injury" from the use of our products in bread over a life span.

The Administrator's counsel also makes the extreme statement that the experimental data on our products "tend to show that polyoxyethylene monostearate is not safe." The Administrator himself found no such thing. If he could have, he presumably would have. His counsel's attempt to stretch the findings into something different from what they actually are is a tacit recognition of the force of our argument that the Administrator had no power to exclude our product on the finding which he actually did make.

Finally, the Administrator's counsel suggests that our Myrj 45 may influence the course of infectious diseases. As we showed in our main Brief, such a possibility is outside the range of fruitful scientific speculation (pp. 57-58). It is, however, typical of the Administrator's entire attempt to justify the discrimination between our products and the mono- and diglycerides that he concludes by mentioning a possibility which, if it did exist for our products, would exist also for the mono- and diglycerides, because such a possibility could only result from surface-activity, a characteristic which the two classes share. *Atlas Brief, p. 57.*

We submit that the Administrator's entire discussion of the safety issue in his Brief (pp. 35-58) is unfounded and fails to justify his discrimination between our products and the competing mono- and diglycerides.

POINT V.

The hearing should be reopened to consider the laboratory experiments on the safety of our products which the Food and Drug Administration has been conducting since 1948.

The Administrator devotes 17 lines of a 72 page brief to his failure to place in the record the safety experiments conducted on the Atlas products by his own expert scientific assistants in the Food and Drug Administration laboratories. *Administrator's Brief, pp. 71-72.* The main burden of his brief discussion is that this evidence is no business of ours—or of the Court's.

It is, of course, perfectly proper for the Food and Drug Administration to conduct such tests on an ingredient proposed for use in a standardized food, *so long as they become*

part of the record on which the decision to include or exclude a food ingredient is made. The free interchange of experimental data between the Food and Drug Administration scientists and the scientists engaged by the proponents of new food ingredients is of great assistance in promoting the program of food technology. Until very recently the Administrator has permitted his scientists to discuss their work on the Atlas products with the scientists engaged by Atlas in accordance with the customs of the profession. The Atlas scientists were advised, among other things, that the Food and Drug Administration's work included the very type of life span multi-level chronic toxicity experiments on Myrj 45 and the other Atlas products which, according to the Administrator's findings and Brief, he considered to be the principal gap in the available safety data on the Atlas materials.

When Atlas filed its petition for review in this Court, however, the scientists of the Food and Drug Administration were forbidden to discuss any phase of the FDA's scientific tests on the Atlas products with the scientists engaged by Atlas. As the Administrator states in his Brief (pp. 71-72), we then urged him to lift this iron curtain and to permit his scientists to advise us as to the status of their tests. Since the Administrator has now called to the attention of the Court our efforts to obtain disclosure, we are reprinting in the Appendix to this Reply Brief the entire correspondence between counsel for Atlas and counsel for the Administrator on this subject. As will be seen from the correspondence, the Administrator has specifically refused to state whether the multi-level chronic toxicity life span experiment on Myrj 45 has been completed, or if not completed, when it will be completed.

Yet, the Administrator has transmitted this same experimental data—withheld from the manufacturer whose products were the subject of the experiments—to the Food Protection Committee of the National Research Council, which is now considering the safety of various classes of surface-active agents in foods. He denies any impropriety in submitting this data to a "distinguished neutral body". *Infra, p. 12a.* We agree with this description of the Food Protection Committee. We believe that the same description would be equally applicable to this Court. But the Administrator refused to give us this material for fear that we would present it to the Court. *Infra, pp. 8a, 12a.*

The Administrator also states in his Brief that before the final order issued, he had before him the Atlas request to reopen the hearing to consider the Food and Drug Administration's own work. He explains that he "asked the Food and Drug Administration if it had any results of tests that would settle the question of safety", and "was informed that the Administration had no such data." *Administrator's Brief, pp. 71-72.*

The issue of whether the Food and Drug Administration's experimental work would "settle" the question of safety is one to be determined by examination of the tests in a reopened hearing and is not for the Administrator or the Food and Drug Administration to determine *ex parte.* It is clear that these tests comprise an important body of scientific data which should properly be a part of the record on which the administrative decision to admit or ban a product is made. The Administration itself has stated that during the course of the extensive tests it has undertaken since 1948, over one thousand animals of several species

have been tested with a wide range of diets to which "synthetic emulsifying agents" were added.*

If the Administrator continues his refusal to inform this Court by placing on the record exactly what data the Food and Drug Administration did have on May 12, 1952, and exactly what data it has today, the Administrator will effectively prevent this Court from performing its proper review function. Two vital questions before this Court are whether:

(a) On May 12, 1952 the Food and Drug Administration's chronic toxicity life span tests or experiments on Myrj 45 were so nearly complete and of such importance that the record should have been reopened to consider this work; and

(b) At the present time the Food and Drug Administration's chronic toxicity life span tests or experiments on Myrj 45 have been completed or are so nearly complete and of such importance that the record should be reopened to consider this work.

If this Court does not know the status of the Food and Drug Administration's own experimental work on May 12, 1952 because the Administrator refuses to tell us or to tell this Court, this Court cannot decide whether the Administrator acted properly in refusing to reopen the record on May 12, 1952. If this Court does not know the status of the Food and Drug Administration's work at the present time because the Administrator refuses to tell us or to tell this Court, this Court cannot decide whether to order the

*Annual Report of the Federal Security Agency, Food and Drug Administration 17 (1951).

Administrator to reopen the record now under Section 701 (f)(2) of the Food, Drug and Cosmetic Act.

CONCLUSION.

The essential issue in this case is whether the Court should set aside the Administrator's order insofar as it excludes the Atlas products from bread and should at the same time direct that the record be reopened.

We believe we have shown that, without regard to any evidence outside the record, the Administrator has made errors of law and illegally discriminated in excluding the Atlas products on both the issue of deception and the issue of safety.

We further contend that apart from the need to correct plain errors on the existing record, the record should be reopened to consider the important new evidence which not only makes the existing record hopelessly stale, but confirms the illegally discriminatory nature of the Administrator's findings. For example, the hearing should be reopened to take evidence on the possible relationship of deception, if any, to levels of use of the Atlas products and competing products, a question on which the existing record is completely barren of any evidence because neither the Government nor any party to the proceeding focused on the question at the time the hearing was held. There should also be evidence, such as we have offered, making direct comparisons between bread baked with the various types of surface-active agents, both in terms of scientific measurement of rates of firming and in terms of actual consumer reactions.

The hearing should also be reopened to permit the introduction of, and cross examination with respect to, the new safety evidence developed by Atlas and by the manufacturers of diacetyl tartaric acid esters (on the basis of which those products have been admitted to the standard), as well as the extensive and unreported tests conducted by the Food and Drug Administration itself.

In asking the Court to reopen the record for the taking of this important new evidence,* we rely on the explicit statutory direction of Section 701 (f)(2) of the Food, Drug and Cosmetic Act that:

> "If the petitioner applies *to the Court* for leave to adduce additional evidence, and shows *to the satisfaction of the Court* that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceedings before the Secretary [now the Administrator], *the Court may order* such additional evidence . . . to be taken before the [Administrator] . . ." (Emphasis added).

In his brief, the Administrator contends that this Court can reverse his refusal to reopen the record only on a showing that the Administrator abused his "discretion." The words of the statute are the short answer to this contention. The statute gives discretion to the *Court* to determine whether a record should be reopened. There was no need under the statute to request the Administrator to reopen the hearing. Consequently, a previous refusal by the Administrator to reopen the record is neither binding nor necessarily persuasive. Since the Food, Drug and Cosmetic Act leaves the question of reopening to the Court, the Ad-

*Petition for Review, p. 16.

ministrator's citations of cases reviewing Interstate Commerce Commission orders, where such a statutory provision as Section 701(f)(2) is not applicable, are beside the point. In the ICC cases, as Mr. Justice Jackson points out, "it has been considered that the discretion to be invoked was that of the body making the order, and not that of the reviewing body." *Interstate Commerce Commission* v. *Jersey City,* 322 U. S. 503, 515, 64 S. Ct. 1129, 1135 (1944). Any other rule would mean that an administrative denial of a motion to reopen completely ousts this Court's jurisdiction under Section 701 (f)(2).

If the Court agrees that it should remand this proceeding for the purpose of correcting the substantial errors committed by the Administrator in light of the existing record or for the purpose of taking important new evidence, or for both reasons, it would be both necessary and appropriate for the Court to continue to stay that part of the Administrator's order which excludes Atlas products from bread. A stay is necessary to prevent irreparable harm, as we demonstrated in our Motion for a Stay, and as this Court agreed in granting the stay. A stay would be appropriate because a finding that the Administrator has committed errors means that the exclusion of the Atlas products from bread is illegal, and because of the prima facie showing that the new evidence to be taken at a reopened hearing will establish both the discrimination inherent in excluding Atlas products from bread and the affirmative propriety of permitting the use of Atlas products as an optional ingredient.

The only unusual factor here is a suggestion that the public health is in danger. Considering the suggestions of danger to public health at face value, however, it is our earnest belief that there is absolutely no risk to the public

from a stay of the Administrator's order pending a further hearing. The best evidence of this fact is that, although our products have been widely consumed for almost six years, not a single example of injury to humans has appeared. The danger at which the Administrator hints is a possibility of harm from consumption of the products in question over a life span. If the Administrator had evidence, or even responsible opinion, that the public health would be jeopardized by continued consumption of our products for the period necessary to complete the hearings, it surely would have been presented and the Administrator surely would not have allowed thirty-two months to elapse between the end of the hearing and publication of his order. Furthermore, if the Administrator really believes that continued consumption of our products may injure health, or if after this Court orders a new hearing the Administrator concludes that health is in jeopardy, he has available ample remedies to protect the public. On the other hand, we have previously submitted to the Court in support of our application for a stay pending review, affidavits of distinguished scientists averring that in their opinion there is no more danger to the public health, long range or short, from continued consumption of our products than from the consumption of the competing products which the Administrator has admitted pending final proof of their safety.

The Administrator's bread standard has been in effect since August 13, except for its exclusion of our product from bread. A continuation of the stay already granted by this Court will not affect the future operation of the standard. But a continuation of the stay will enable the Admin-

istrator to do what he has not done—to perform his duties equitably, legally and without discrimination.

Respectfully submitted,

OSCAR COX

1210 18th Street, N. W.
Washington 6, D. C.
Attorney for Petitioner

C. C. GAMMONS,
KENNETH E. MULFORD,
ROGER R. HORTON,
Delaware Trust Co. Bldg.,
Wilmington, Delaware.
LLOYD N. CUTLER,
LOUIS F. OBERDORFER,
HERBERT L. PACKER,
DONALD F. TURNER,
1210 18th Street, N. W.,
Washington 6, D. C.,
Of Counsel.

APPENDIX

Letterhead of

COX, LANGFORD, STODDARD & CUTLER

July 9, 1952

Hon. Oscar R. Ewing
Federal Security Administrator
Washington 25, D. C.

Re: *Atlas Powder Company* v. *Ewing*

Dear Mr. Ewing:

As you know, Atlas Powder Company has petitioned the Court of Appeals for the Third Circuit to review your order issued May 12, 1952, establishing a standard of identity for bread and rolls, insofar as that order prohibits the use in bread and rolls of certain surface-active materials manufactured by Atlas Powder Company.

The Atlas materials used in bread are members of a general group of materials manufactured by Atlas and used in a number of other food products, including ice cream. For the past several years, Atlas has been sponsoring an extensive program of scientific studies designed to determine whether there is any reasonable likelihood of injury from the use of Atlas materials to persons consuming these materials regularly over a life span in the amounts in which they are used in various foods.

These studies are being continued despite the fact that Atlas believes, as a result of studies already completed, that it has already established the safety of its materials. The studies are being continued in order to convince the Food & Drug Administration, the Food Protection Committee of the National Research Council, and other interested scientific bodies that our materials can be safely and beneficially used in foods. In the very nature of things, these studies may

never be "completed" in any final sense, but may continue for some time. The number of questions which recent scientific developments have raised and can continue to raise about any and all food ingredients is likely to outstrip even the developing capacity of modern scientific techniques available to answer these questions.

The Atlas-sponsored studies are being conducted by various eminent and independent scientists at university and private laboratories throughout the country, with the cost of the work, of course, being assumed by Atlas. The studies being conducted are of the general types recommended by Dr. Lehman and his associates in the Food & Drug Administration, both in general publications relating to testing procedures for all food ingredients and in specific discussions with members of the Atlas scientific staff as to desirable studies for the Atlas materials. Most of the independent scientists engaged to conduct these studies have at our suggestion discussed both the original plan and the subsequent progress of their work with Dr. Lehman and his staff.

These meetings and conversations at the scientific level have, of course, involved a general and frank exchange of detailed information as to the progress of scientific experiments and the interpretation of particular data, including experiments being conducted and data being compiled by the Food & Drug Administration laboratories in their own experiments on the Atlas materials. This is the generally accepted custom in all fields of scientific research. It has been of great benefit to the Atlas scientific staff and to the independent scientists engaged by Atlas in planning and directing the course of the Atlas-sponsored experiment program. We hope that these meetings have also been of benefit to the Food & Drug Administration's scientific staff in planning and directing their own experiments on the Atlas materials and in furnishing expert scientific advice to the Food & Drug Commissioner and to you.

This free exchange of information and the mutual discussions to plan experiments, report results and interpret data were abruptly terminated shortly after Atlas advised the Food & Drug Administration of its intention to file a petition for review of the Federal Security Administrator's order, published in the *Federal Register* for May 15, 1952, establishing a standard of identity for bread and rolls. Both the Food & Drug Administration scientists and the Commissioner of Food & Drugs himself advised us that the decision to terminate the free interchange of scientific information was made on recommendation of your General Counsel's office because of the fact that the parties were "in litigation."

In subsequent discussions with your General Counsel, Mr. Alanson Willcox, he has advised us in substance that the reason for this recommendation was that one ground cited in support of our petition for review is your failure to reopen the record to consider the results of certain long-term chronic toxicity experimental studies of the Atlas materials which had recently been conducted by the Food & Drug Administration's staff. He stated that the scientific discussions had been terminated because Atlas might choose to call to the attention of the Court information as to these chronic toxicity tests obtained as a result of continuing the discussions. Mr. Willcox stated that in his opinion it would be improper to call to the Court's attention any information dealing with events occurring after May 15, 1952, and that the best way of preventing Atlas from calling such information to the Court's attention would be to deny the information to Atlas by shutting off the scientific discussions.

We advised Mr. Willcox that we desired to have the scientific discussions continue for reasons unconnected with the present Court action. We pointed out that we have gone to great expense to finance independent scientific experiments for the purpose of obtaining expert opinions from independent scientists as to the safety of our materials, and

that these scientists could hardly be expected to express their opinions when highly pertinent scientific information available in the field was being denied to them and when they are forbidden to discuss the subject with Government experts.

We also pointed out that in the immediate future the independent scientists working on Atlas-sponsored programs will be called upon to present their work and their opinions to the Food Protection Committee of the National Research Council, that the National Research Council will probably also be receiving data and opinions from the staff of the Food & Drug Administration, and that the independent scientists engaged in the Atlas experimental program will thus be in the position of presenting data to the Food Protection Committee which the Food Protection Committee will be comparing with secret data and opinions received from the Food & Drug Administration, of which these independent scientists have no knowledge and which they have been forbidden to discuss with the Government scientists who did the work.

We pointed out that this method of conducting scientific research and arriving at scientific conclusions is at variance with recognized and accepted scientific procedures in all but the most highly classified military fields; that it is at variance with the Food & Drug Administration's own established policy of freely discussing and exchanging scientific data with interested manufacturers and outside scientists; and that it can be interpreted as a reprisal against the Atlas Powder Company for exercising its legal right to seek a Court review of a food standard order, and for raising with the Court the perfectly legitimate question of whether it was erroneous to refuse to reopen the record in order to consider important work on the Atlas materials recently performed in your laboratories. In the long run, a policy of nondisclosure can only retard the progress of scientific knowledge on this imoprtant subject, a result which can hardly be viewed as in the public interest.

We also pointed out that while our major objective in requesting a resumption of scientific discussions was not related to the current appeal, we could not properly agree, as a condition of resuming these discussions, that we would refrain from calling to the attention of the Court any pertinent information which might result from these discussions, and which might be relevant to the issues in the present appeal. If these discussions would lead to the disclosure of information that is relevant to the issues involved in the present appeal, we believe that you yourself would not want to be in the position of withholding such information from the Court. If we believe the information is relevant and can properly be called to the Court's attention, and your legal advisors disagree as to the relevancy of the information or as to whether the Court can properly take notice of such information in the present posture of the appeal, we believe that any such disagreement can safely be left to the judgment of the Court.

At the end of our conference with Mr. Willcox, he requested us to submit a specific request in writing, stating the exact nature of our request and also setting forth any conditions to which we might agree for withholding from the Court any information obtained during such discussions.

Our specific requests are as follows:

1. We request that Dr. Lehman and his staff be authorized to carry on scientific discussions with the scientific staff of the Atlas Powder Company and independent scientists carrying on Atlas-sponsored experimental studies, in the same manner and with the same freedom of exchange that existed before May 15, 1952.

2. If this request is denied, we request that we be advised in writing of the current status of the long-term chronic toxicity feeding studies conducted on Myrj 45, Span 60 and Tween 60 by the laboratories of the Food & Drug Administration, including the following specific information separately stated as to each material:

(a) When the studies began.

(b) When the feeding of the animals terminated or is scheduled to terminate.

(c) A description of the number of animals used, the level fed, the make-up of the diet and other relevant conditions of the experiment.

(d) The results observed during feeding period, such as weight and general physical condition.

(e) The results of any autopsies, histologies, or other post-feeding work conducted to date.

(f) The present interpretation of the scientists conducting the experiments as to the meaning of the results.

(g) The date of completion of the study, or the scheduled date of completion.

(h) The date of completion of the written report describing the study, or the scheduled dated of completion.

(i) Copies of whatever data relating to these studies has been submitted to the Food Protection Committee of the National Research Council.

3. If request 2 is denied, we respectfully request the same information as of May 15, 1952.

We have to advise you that we cannot agree to any conditions to be placed upon the use in the present review proceedings of any information obtained pursuant to the above requests. In the event we elect to call any such information to the attention of the Court, and you believe that such information should not properly be placed before the

Court, we would expect you to present your objections to the Court. We believe the Court will resolve any such question in a manner which fully protects the rights of the Government.

Sincerely yours,

(s) Cox, Langford, Stoddard & Cutler
Cox, LANGFORD, STODDARD & CUTLER
Attorneys for Atlas Powder Company

FEDERAL SECURITY AGENCY

WASHINGTON

July 16, 1952

Office of the
Administrator

General Counsel

Dear Mr. Cox:

I have discussed with Mr. Ewing your letter of July 9 to him, and he asked me to convey to you his decision on the matter.

If during the pendency of the litigation the investigatory work of the Food and Drug Administration should develop facts which caused Mr. Ewing to believe that your client's products are safe for use in bread, he would of course feel obligated to call that development at once to the attention of the Court. Except for that possibility, Mr. Ewing agrees with the view I have expressed to you orally, that any further discussions between the scientists of your client and those of the Food and Drug Administration should be postponed until after the conclusion of the litigation.

Our purpose is to protect the public interest, as we see it, by bringing the present litigation to an end, and thus securing removal of inadequately tested materials from bread, at the earliest possible time.

Investigations by the Food and Drug Administration of the safety of Myrj 45, Tween 60 and Span 60 have not yet been completed, and I am told will not be completed until some time in 1953. That being the case, what you are asking is that we enable you to present to the Court, at second hand, the results of uncompleted work

of our scientists, from which they are not yet ready to draw conclusions. I do not think that is a reasonable request.

Sincerely yours,
/s/ Alanson W. Willcox
Alanson W. Willcox
General Counsel

Mr. Oscar Cox
Cox, Langford, Stoddard & Cutler
1210 18th Street, N. W.
Washington 6, D. C.

Re: *Atlas Powder Company* v. *Ewing*

Letterhead of

COX, LANGFORD, STODDARD & CUTLER

July 18, 1952

Alanson W. Willcox, Esq.
General Counsel
Federal Security Agency
Washington 25, D. C.

Re: *Atlas Powder Company* v. *Ewing*

Dear Mr. Willcox:

We have received your letter of July 16, 1952 advising that the Administrator has denied our request to lift the ban on free scientific interchange which you have imposed on the scientists employed by the Food and Drug Administration.

Your letter states as a reason for denying our request that investigations by the Food and Drug Administration of the safety of Myrj 45, Tween 60 and Span 60 have not yet been completed and will not be completed until some time in 1953. The principal Atlas material used in bread is Myrj 45. We had previously been informed that the two-year chronic toxicity test on Myrj 45 had been completed. Although our letter of July 9 specifically asks whether this information as to the Myrj 45 tests is correct, your reply groups the work on Myrj 45, Span 60 and Tween 60 together, and does not specifically state whether all or part of the work on Myrj 45 alone is completed. We therefore respectfully renew our questions as to the status of the work on Myrj 45.

Your letter does not deal specifically with the detailed requests contained in our letter of July 9, 1952, but rejects all of them as "unreasonable". One of the requests was for copies of whatever data the Food and Drug Administration has submitted to the National Research Council concerning the safety of our products. Unless we have been mis-

informed, at least some of the Food and Drug Administration's data on our materials has recently been submitted to the National Research Council. It would therefore appear that the work of your scientists is not completely unevaluated and it would further appear that to some extent your scientists are "ready to draw conclusions." We therefore do not see how a request for the data you have submitted to the National Research Council can possibly be considered unreasonable, and we respectfully renew that request for your consideration.

Sincerely yours,

OSCAR COX

FEDERAL SECURITY AGENCY
WASHINGTON
July 28, 1952

Office of
The Administrator
General Counsel

Dear Mr. Cox:

I have your letter of July 18 with further reference to your request to continue discussion between the scientists of your client and those of the Food and Drug Administration.

The statement in my letter of July 16, that investigations by the Food and Drug Administration of the safety of Myrj 45, Tween 60 and Span 60 have not been completed, was intended to apply to each of the products separately as well as to the group. In the case of each product, some individual tests have been completed, some are in process, and some are in contemplation which have not yet been started. All of this work is expected to shed light, among other things, on the safety of the products in question, and it is not correct to speak of any particular completed test as resolving this issue.

I see nothing inconsistent with the foregoing in the fact that the Food and Drug Administration has submitted data to the National Research Council, nor any implication from such submittal that we have reached any conclusions. Nor do I see any impropriety in submitting to a distinguished neutral body uncompleted materials which we are not willing to submit to your client for presentation to the Court.

Sincerely yours,

/s/ Alanson W. Willcox
General Counsel

Mr. Oscar Cox
Cox, Langford, Stoddard & Cutler
1210 18th Street, N. W.
Washington 6, D. C.

Re: *Atlas Powder Company* v. *Ewing*

Office-Supreme Court, U.S.
FILED
FEB 17 1953
HAROLD B. WILLEY, Clerk

IN THE

Supreme Court of the United States

OCTOBER TERM, 1952

No. 610

ATLAS POWDER COMPANY, a Corporation,
Petitioner,

v.

OSCAR R. EWING, Federal Security Administrator,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

OSCAR COX,
1210 18th Street, N. W.,
Washington 6, D. C.
Attorney for Petitioner.

C. C. GAMMONS,
KENNETH E. MULFORD,
ROGER R. HORTON,
Delaware Trust Co. Bldg.,
Wilmington, Delaware.

EZEKIEL G. STODDARD,
LLOYD N. CUTLER,
LOUIS F. OBERDORFER,
HERBERT L. PACKER,
WILLIAM R. PERLIK,
1210 18th Street, N. W.,
Washington 6, D. C.
Of Counsel.

INDEX

PAGE

Opinions Below 1

Jurisdiction 2

Questions Presented 2

Statute Involved 2

Statement of the Case 3

Reasons for Granting the Writ 8

I. By ruling that Congress authorized the Federal Security Administrator, in promulgating a standard of identity for food, to banish an established food ingredient from the market on a negative finding that the record did not justify its continued use—rather than an affirmative finding that the record justified its banishment—the Court of Appeals decided a novel and important question of Federal law which has not been, but should be, resolved by this Court..... 8

II. The decision of the Court below that a crucial finding of fact made by the Administrator was sustainable even though unsupported by any evidence of record is in conflict with applicable decisions of this Court..... 20

III. Contrary to the plain language of the Food, Drug, and Cosmetic Act, as well as prior decisions of this Court, the Court of Appeals denied an application for leave to adduce additional evidence without independently determining the materiality of that evidence..... 23

Conclusion 27

Appendix A 1a

AUTHORITIES CITED

CASES: PAGE

Addison v. *Holly Hill Fruit Products, Inc.*, 322 U. S. 607 (1944) 17, 18
Anniston Manufacturing Co. v. *Davis*, 301 U. S. 337 (1937) 9
Atchison, T. & S. F. Ry. Co. v. *United States*, 284 U. S. 248 (1932) 23

Crane v. *Commissioner*, 331 U. S. 1 (1947) 17
Cream Wipt Food Products Co. v. *Federal Security Administrator*, 187 F. 2d 789 (3d cir. 1951) 22

Duparquet Huot & Moneuse Co. v. *Evans*, 297 U. S. 216 (1936) 13

F. P. C. v. *Panhandle Eastern Pipe Line Co.*, 337 U. S. 498 (1949) 17, 18
Federal Security Administrator v. *Quaker Oats Co.*, 318 U. S. 218 (1943) 8, 18, 19
F. T. C. v. *Morton Salt Co.*, 334 U. S. 37 (1948) .. 8, 9

I. C. C. v. *City of Jersey City*, 322 U. S. 503 (1944) 23

N. L. R. B. v. *Donnelly Garment Co.*, 330 U. S. 219 (1947) 24
N. L. R. B. v. *Indiana & Michigan Electric Co.*, 318 U. S. 9 (1943) 24, 26
N. L. R. B. v. *Mexia Textile Mills, Inc.*, 339 U. S. 563 (1950) 24

Phelps-Dodge Corp. v. *N. L. R. B.*, 313 U. S. 177 (1941) 10

Saginaw Broadcasting Co. v. *F. C. C.*, 96 F. 2d 554 (D. C. Cir. 1938) 18
S. E. C. v. *Chenery Corp.*, 318 U. S. 80 (1943) . 10, 18, 22

PAGE

62 Cases of Jam v. *United States*, 340 U. S. 593 (1951) 11
Southport Petroleum Co. v. *N. L. R. B.*, 315 U. S. 100 (1942) 24
United States v. *Cardiff*, 344 U. S. 174 (1952) 18
United States v. *Lexington Mill & Elevator Co.*, 232 U. S. 658 (1914) 18 15
Universal Camera Corp. v. *N. L. R. B.*, 340 U. S. 474 (1951) 22

STATUTES:

Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040 *et seq.*, 21 U. S. C. 301, *et seq.*
Section 201(p) 14, 1a
301 .....12, 2a
302 .....15, 2a
303 .....12, 15, 3a
304 .....15, 3a
401 .....2, 12-20, 4a
402 .....15, 5a
403 .....15, 7a
403(g) 12, 8a
505 .....13, 11a
505(d)(1) 13, 12a
(2) 13, 12a
(3) 13, 13a
(4) 13, 13a
505(e) 14, 13a
701(e) 12, 19, 16a
(f)(1) 12, 16a
(f)(2) 2, 6, 23-26, 17a
Food and Drug Act of 1906, Sections 1-5, 7-15, 34 Stat. 768 *et seq.* (1906), 21 U. S. C. 1-5, 7-15... 14
Federal Trade Commission Act, Section 5(c), 38 Stat. 717, 719 (1914), 15 U. S. C. 45(c)..... 26

PAGE

Investment Company Act of 1940, Section 42(a), 54 Stat. 789, 844 (1940), 15 U. S. C. 80a-42(a). 26
Judicial Review Act of 1950, Section 7(c), 64 Stat. 1129, 1130 (1950), 5 U. S. C. 1037(c)..... 26
Labor Management Relations Act of 1947, Section 10(e), 61 Stat. 136, 146 (1947), 29 U. S. C. 160(e) 26
Public Utility Act of 1935, Section 24(a), 49 Stat. 803, 834 (1935), 15 U. S. C. 79x(a)..... 26
Securities Act of 1933, Section 9(a), 48 Stat. 74, 80 (1933), 15 U. S. C. 77i(a)..... 26
Securities Exchange Act of 1934, Section 25(a), 48 Stat. 881, 901 (1934), 15 U. S. C. 78y(a)..... 26
Trust Indenture Act of 1939, Section 322(a), 53 Stat. 1149, 1175 (1939), 15 U. S. C. 77vvv(a).. 26

MISCELLANEOUS:

DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT (1938) 14
Executive Order No. 9835, 12 Fed. Reg. 1935, 1938 (1947) 9
Executive Order No. 10241, 16 Fed. Reg. 3690 (1950) 9
Fuchs, *The Formulation and Review of Regulations under the Food, Drug and Cosmetic Act,* 6 LAW AND CONTEMPORARY PROBLEMS 43 (1939)..... 10
Hearings Before the House Select Committee to Investigate the Use of Chemicals in Food Products, 81st Cong., 2d Sess. (1950) 18
H. R. 3257, 82d Cong., 1st Sess. (1951)..... 17
H. R. 2245, 83d Cong., 1st Sess. (Jan. 29, 1953), printed in Appendix A 17, 19a
H. R. Rep. 2139, 75th Cong., 2d Sess. (1938)..... 16
H. R. Rep. 3254, 81st Cong., 2d Sess. (1951) 18
H. R. Rep. 2356, 82d Cong., 2d Sess. (June 30, 1952) 17
U. S. Civil Service Commission Press Release, Dec. 17, 1951 9

IN THE

Supreme Court of the United States

OCTOBER TERM, 1952

No.

ATLAS POWDER COMPANY, a Corporation,
Petitioner,

v.

OSCAR R. EWING, Federal Security Administrator,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Petitioner prays that a Writ of Certiorari issue to review the judgment of the United States Court of Appeals for the Third Circuit, entered in the above-entitled case on December 22, 1952.

OPINIONS BELOW

The order and memorandum opinion of the Respondent, Federal Security Administrator, are reported in 17 Fed. Reg. 4453, 4467 (R. 458, 476). The opinion of the Court of Appeals (R. 3283) is not yet reported.

JURISDICTION

The judgment of the Court of Appeals was entered on December 22, 1952. A petition for rehearing was denied on January 14, 1953. The jurisdiction of this Court is invoked under 28 U. S. C. 1254(1).

QUESTIONS PRESENTED

1. Whether Congress intended, by Section 401 of the Food, Drug, and Cosmetic Act, to empower the Federal Security Administrator to banish an established ingredient from a standardized food on the negative finding that he could not conclude that there is no likelihood of injury from the use of the ingredient when consumed over a life span.

2. Whether an administrative finding essential to the validity of a purported distinction between two fundamentally similar and competing food ingredients, invoked to permit the use of one ingredient in a standardized food and to exclude the other, may be made as a matter of administrative judgment without *any* supporting evidence.

3. Whether a Court of Appeals may deny a request for leave to adduce additional evidence under Section 701(f)(2) of the Food, Drug, and Cosmetic Act without independently determining the materiality of the evidence so offered.

STATUTE INVOLVED

The pertinent provisions of the Food, Drug, and Cosmetic Act are printed in Appendix A, *infra*.

STATEMENT OF THE CASE

Petitioner, Atlas Powder Company, manufactures a food ingredient which has been widely marketed to the baking trade under the name of Myrj 45. Myrj 45 is an "emulsifier"—a substance which helps dissimilar materials such as oil and water to mix with each other. Myrj 45 in commercially baked white bread keeps the bread softer for a longer period of time than would otherwise be the case (R. 742). This ingredient was introduced for use in bread in 1947 after years of research by Atlas and others engaged in the field of food technology (R. 733, 748). The object widely sought was to provide a loaf of bread for the consumer which would stay soft and palatable for as long as possible after baking, thus prolonging the life of the bread, and reducing economic waste. For several years before the introduction of our product bakers had used other products, including a type known as mono- and diglycerides, to achieve the same result (R. 674-675, 753). The introduction of our type of product early in 1947 met with widespread acceptance among bakers (R. 2786, 2811, 2828, 2890-2891) and it very soon began to make deep inroads on the market previously enjoyed by the producers of mono- and diglycerides.

In 1948, the Federal Security Administrator* resumed a series of hearings which were begun in 1941 and were designed to fix definitions and standards of identity for commercially baked white bread, under Section 401 of the Food, Drug, and Cosmetic Act, *infra*, p. 4a. Once such a standard has been promulgated for a food, it becomes

*The administration of the Food, Drug, and Cosmetic Act was transferred from the Secretary of Agriculture to the Federal Security Administrator by Reorganization Plan IV, section 12, set out in note to Section 133t of Title 5, U. S. C. (1946).

unlawful to sell that food in interstate commerce if it contains an ingredient not specifically permitted by the standard. Under the hearing procedure employed by the Federal Security Administrator, anyone who wishes to have a particular ingredient included in a food standard appears at the hearing and presents evidence about the ingredient's use in the particular food. All other persons who appear at the hearings, whatever their purpose, enjoy a virtually unlimited right of cross-examination. Atlas presented witnesses in support of the suitability of Myrj 45 for use in bread. Atlas' competitors extensively cross-examined these witnesses in an attempt to discredit the use of Myrj 45 in bread (*e. g.*, R. 1316-1358). In addition, some of these competitors introduced witnesses of their own who presented opinion evidence as to the alleged unsuitability of Myrj 45 (*e. g.*, R. 2906-2936).

The hearings closed on September 20, 1949. On August 8, 1950, the Administrator promulgated a proposed order, excluding Myrj 45 as an optional ingredient in bread at any level. The Administrator based his tentative exclusion of Myrj 45 on the two grounds that:

> (a) Its use at any level tends to deceive consumers by making them think that the bread in which it is used is not so old as it actually is (R. 14); and
>
> (b) Although "there has been no definite evidence of injury" from the use of Myrj 45 and other Atlas products in bread,* "the investigational work does

*Petitioner proposed several emulsifiers manufactured by it for inclusion as optional ingredients in bread. This review proceeding concerns only Myrj 45, the principal Atlas emulsifier sold for use in bread.

not definitely establish their safety, and the record does not permit a conclusion that bread containing them is safe for continuous use over the human life span" (R. 15).

The Administrator failed to make any tentative findings on either of these two issues as to the competing mono- and diglycerides. Nevertheless, his proposed order admitted them to the standard at a maximum level of 25% of the shortening content of bread (R. 5-6).

In October, 1950, Atlas filed a motion to re-open the record, pointing out the Administrator's failure to apply similar criteria to the competing mono- and diglycerides, and offering new evidence to show that the two classes of products were comparable in all essential respects relating to the issues of safety and deception (R. 19). From time to time thereafter, Atlas supplemented its motion to re-open with further offers of proof (*e.g.*, R. 177, 201, 210, 284, 389). It also requested that the hearing be re-opened to receive as evidence tests conducted by Food and Drug Administration scientists on the suitability of Myrj 45 (R. 347).

On May 15, 1952, the Administrator published a memorandum opinion denying Atlas' motion to re-open the record (R. 476). At the same time, he published his final order prescribing definitions and standards of identity for bread (R. 458).

The Administrator's final order excluded Myrj 45 on substantially the same "safety" and "deception" considerations as underlay his 1950 order (R. 14, 15, 472, 473). The same order excluding Myrj 45 from the food standard admitted the competing mono- and diglycerides.

The Administrator's final order differed from his proposed order in several respects. The final order reduced

the permitted level of mono- and diglycerides to 20% of the shortening content. The Administrator admitted that the 25% level set in the tentative order might cause deception "such as sometimes occurs" when Myrj 45 is used (R. 460, 461), but found that the 20% level would be non-deceptive (R. 461). He also conceded in his final finding that certain safety aspects of the mono- and diglycerides (their surface-active effects before digestion) "have not been adequately investigated to permit a final decision that they are safe for use in bread which is regularly consumed in a life span" (R. 468). He nevertheless permitted the continued use of mono- and diglycerides pending a re-opened hearing at some time in the future at which evidence of their safety could be considered (R. 473A). But he refused Myrj 45 continued access to the market. He excluded it on the combined grounds of deception and safety. On safety he found that "there was no definite evidence of injury" from the use of Myrj 45 in bread, but he excluded it from use in bread on the negative finding that:

> "the results of the pharmacological tests reported do not warrant the conclusion that there is no likelihood of injury from bread containing these substances in the amounts proposed to persons consuming it continuously over a life span" (R. 473).

On May 22, 1952, Atlas sought review of the Administrator's order in the Court of Appeals for the Third Circuit (R. 3234). Atlas requested that Court to set aside the Administrator's order and to exercise its statutory function under Section 701(f)(2) of the Food, Drug, and Cosmetic Act of directing the Administrator to receive pertinent additional evidence which had developed since the close of the

hearings in September 1949 (R. 3234, 3249). At the same time, Atlas also applied for a stay of the Administrator's order (R. 3252). Following oral argument and the consideration of briefs submitted by both parties, the Court of Appeals, on June 10, 1952, granted a stay (R. 3282), which remains in effect until the conclusion of the review proceedings.

On December 22, 1952, the Court of Appeals affirmed the Administrator's order (R. 3299). It approved the Administrator's exclusion of Myrj 45 from the bread standard on the negative finding that Atlas had not proven that there was no likelihood of injury from its use over a life span (R. 3294).* The Court also held that the Administrator could lawfully eliminate Myrj 45 as deceptive and at the same time include the mono- and diglycerides by setting a "non-deceptive" level for their use simply as a matter of administrative judgment and without evidentiary support (R. 3295). Finally, the Court, without making its own independent determination, accepted the Administrator's conclusion that the results of tests on the safety of Myrj 45 conducted in the Food and Drug Administration's own laboratories since the close of the hearings in 1949 did not constitute material additional evidence (R. 3297-8).

---

*The Court's handling of the two prime issues of safety and deception shows that its error on either issue is a sufficient ground, standing alone, for reversal of its decision approving the Administrator's action. The Court of Appeals has stated that "risk of injury to health and risk of deception as to bread age were *both* relevant matters before the Administrator, and *the combined weight of proper findings in both regards led to the exclusion of petitioner's products*" (R. 3296, emphasis supplied).

REASONS FOR GRANTING THE WRIT

I.

By ruling that Congress authorized the Federal Security Administrator, in promulgating a standard of identity for food, to banish an established food ingredient from the market on a negative finding that the record did not justify its continued use—rather than an affirmative finding that the record justified its banishment—the Court of Appeals decided a novel and important question of Federal law which has not been, but should be, resolved by this Court.

A. Importance of the Question.

The Court of Appeals has rendered an important and far reaching decision about the extent of the power conferred by Congress to banish an established food ingredient from the market by administrative action establishing standards of identity.

In this case the Federal Security Administrator ruled that although "the record shows no definite evidence of injury" from the use of Myrj 45 and related Atlas products in the amounts in which they are likely to occur in bread, "the results of the pharmacological tests reported do not warrant the conclusion that there is no likelihood of injury from bread containing these substances in the amounts proposed to persons consuming it continuously over a life span" (R. 473). On the strength of this negative finding*

*This negative finding differs materially from the finding at issue in *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U. S. 218, 220 (1943) where the Administrator supported his order by the *affirmative* finding that Quaker Oats enriched farina "would tend to confuse and mislead." See also *F. T. C.* v. *Morton Salt Co.*, 334 U. S. 37 (1948).

the Administrator eliminated the petitioner's products from a market which they had enjoyed since 1947.*

If the Administrator has this power, he can banish an established ingredient from the market without any evidence at all showing affirmatively that there is reasonable likelihood of injury from the ingredient's use. Instead he can impose on food producers "the inherently impossible" task of trying to prove the negative that there is no likelihood of injury. *Cf. Anniston Manufacturing Co.* v. *Davis*, 301 U. S. 337, 352-354 (1937). Such a difference in the measure of proof, "as every lawyer knows, is not unimportant and in many cases would be decisive." *Cf.* Jackson, J. dissenting in part in *F. T. C.* v. *Morton Salt Co.*, 334 U. S. 37, 55, 56 (1948).** No matter how much testing a food producer may do, it would be virtually impossible to prove, for example, that there is no likelihood of injury from use in foods of salt, flour, or Myrj 45 because it cannot be proven that there is no likelihood that they do not have some

---

*The administrative action under review here affects the use of our products in commercially baked white bread and rolls only. Our products will continue to be used in other foods for which no standards have yet been established.

**A dramatic illustration of the effect of a slight difference in the measure of proof is the difference between the Executive Orders outlining the responsibility of the President's loyalty boards. An order promulgated in 1947 authorized dismissal of Federal employees where there were "reasonable grounds . . . for belief that the person involved is disloyal." Executive Order No. 9835, 12 Fed. Reg. 1935, 1938 (1947). In 1951 this order was amended to authorize dismissal where there was a "reasonable doubt" as to loyalty. Executive Order No. 10241, 16 Fed. Reg. 3690 (1951). The difference between these standards is not so sharp as the difference between an affirmative and a negative finding. Yet the substantial effect of this change in the measure of proof is shown by the fact that within six months after the amendment of the Executive Order, the Loyalty Review Board announced that 565 cases which had been decided under the old standard were ordered reopened for review in the light of the new standard. U. S. Civil Service Commission Press Release, December 17, 1951.

relationship to multiple sclerosis or cancer, since all of the causes of these diseases are not known. It would take decades to set at rest the hundreds of questions that can be asked about any food or food ingredient—questions which may be motivated by honest scientific doubts or by the desire of entrenched competitors to preserve their competitive advantages. Atlas and other producers of food ingredients already spend large amounts on the difficult and time-consuming experiments required to test the safety of their products. If the additional burden of proving a negative is to be placed on producers of new and useful ingredients, Congress, not the Administrator, should make the decision to impose that burden.

Moreover, the power to act on the basis of a negative finding virtually deprives food producers of their right to a "high degree of judicial review,"* and prevents appellate courts from exercising their statutory duty to insure that the Administrator's findings are supported by substantial evidence. *Cf. Phelps-Dodge Corp.* v. *N. L. R. B.*, 313 U. S. 177, 197 (1941); see also *S. E. C.* v. *Chenery Corp.*, 318 U. S. 80 (1943). If the Administrator merely has to say to a food producer, "You have not convinced me that there is no likelihood of harm from your product," there is no effective way in which a Court can measure the conclusion against the supporting evidence. It is virtually impossible, for example, to make an intelligent judicial review of the Administrator's distinction between mono- and diglycerides and Myrj 45, when he admitted the former and excluded

---

*See Fuchs, *The Formulation and Review of Regulations Under the Food, Drug, and Cosmetic Act*, 6 LAW AND CONTEMPORARY PROBLEMS 43 (1939).

the latter on negative findings as nearly identical as the two quoted below:

> *Mono- and Diglycerides.*
>
> "their surface-active effects before digestion have not been adequately investigated to permit a final decision that they are safe for use in bread which is regularly consumed in a life span" (R. 468).
>
> *Myrj 45.*
>
> "the results of the pharmacological tests reported do not warrant the conclusion that there is no likelihood of injury from bread containing these substances in the amounts proposed to persons consuming it continuously over a life span" (R. 473).

This vast unreviewable power would extend to every ingredient in foods which the Administrator determined to standardize, whether the food ingredient be old or new, natural or chemical, agricultural or industrial.

The novel question here is whether Congress intended to confer this kind of power upon the Administrator in a food standard proceeding. We contend that Congress did not. In his "anxiety to effectuate the congressional purpose of protecting the public" the Administrator has extended "the scope of the statute beyond the point where Congress indicated it would stop," *cf. 62 Cases of Jam* v. *United States,* 340 U. S. 593, 600 (1951), and has persuaded the Court of Appeals to approve the extension. We submit that a determination of such far reaching implications deserves a plenary review by this Court.

B. The food standard statute authorizes banishment of an established food ingredient only on an affirmative finding that the ingredient is unsuitable—not a negative finding that suitability has not been proved.

The Administrator acted here under the authority of Section 401 of the Federal Food, Drug, and Cosmetic Act of 1938. This section provides, in applicable part:

> "Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food . . . a reasonable definition and standard of identity . . ."

This section is supplemented by Section 701(e) which affords a hearing to any interested person and requires that a food standard order be based "only on substantial evidence of record at the hearing." Section 701(e) further requires the Administrator to set forth as part of the order "*detailed* findings of fact on which the order is based." (Emphasis supplied.) Section 701(f)(1) gives to any person adversely affected by the standard the right to judicial review by a Court of Appeals, provided that "the findings . . . as to the facts, if supported by substantial evidence, shall be conclusive." When a food standard so adopted and approved becomes effective without including a particular product, interstate sale of a standardized food containing that product immediately becomes illegal, no matter how long the product has been used in that food. Sections 301, 303, 403(g).

The language of Sections 401 and 701 and their legislative histories do not even intimate that Congress intended to grant to the Administrator the sweeping power to

eliminate a product already in food on a negative finding that its suitability has not been proven, rather than an affirmative finding that its unsuitability has been proven. Analysis of "the structure of the statute, and the relation, physical and logical, between its several parts" shows that Congress did not intend to give this broad power in the food standard provision. *Cf. Duparquet Huot & Moneuse Co.* v. *Evans,* 297 U. S. 216, 218 (1936).

The clearest demonstration of the limits on the Administrator's powers appears by a comparison of the food standard provision (Section 401), which does not specifically authorize negative findings, and the new drug provision (Section 505), which does. Both of these provisions were enacted at the same time as part of an integrated and comprehensive scheme for federal supervision of the food, drug, and cosmetic industries.

Congress after full and careful consideration specifically gave the Administrator the power to exclude *new drugs* on a negative finding. In order to prevent the sale and consumption of new drugs until they have been thoroughly tested, Section 505 of the Act provides that no new drug may be sold or used until it has first been approved by the Administrator. And the new drug section specifically authorizes the refusal of an application upon a negative finding. For example, a new drug application may be refused approval because the Administrator determines that "he has insufficient information to determine whether [it] is safe." Section 505(d)(4). See also Sections 505(d)(1), (2) and (3).

Congress after long and extensive hearings and careful thought realized the far reaching implications of its grant of power to act on a negative finding in the new drug

section.* It therefore specifically limited the circumstances in which a negative finding can be used. Congress expressly provided that drugs lawfully on the market before 1938 cannot be removed at all by administrative action.** Pre-1938 drugs can be removed only in a civil or criminal court proceeding in which the Administrator has the burden of proving beyond a reasonable doubt or by a preponderance of the evidence an *affirmative* harmfulness or tendency to harm, or an *affirmative* deception or tendency to deceive. Once a new drug application has been approved, it may be suspended only if the Administrator *affirmatively* finds that the drug is "unsafe" or that the application was originally granted in reliance on a material misstatement. Section 505(e). And such an affirmative finding that an approved drug is "unsafe" can be the basis for suspension of such approval only where lack of safety is shown by new testing methods or by testing methods not deemed reasonably applicable when the application became effective. *Ibid.* These strict limitations on the use of negative findings in the new drug provisions show that Congress would not have authorized their use by silence in the provisions of the Act relating to foods.

The new drug section requires an Executive license before a new drug can be used, and authorizes refusal of a license on the basis of a negative finding. The food standard

---

*The Food, Drug, and Cosmetic Act was the product of the deliberation of several Congresses. The legislative history is collected in DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT (1938).

**The Act excluded from the new drug definition any drugs if, before the enactment of the 1938 Act, they were subject to the provisions of the 1906 Pure Food and Drug Act and if thereafter their labeling contained the same representations concerning the conditions of their use. Section 201(p). The 1906 Act contained provisions authorizing civil and criminal action against adulterated and misbranded drugs. 34 Stat. 768, *et seq.* (1906), 21 U. S. C. former sections 1-5, 7-15.

section does not require an Executive license before an ingredient can be used; it authorizes the Executive to banish a use already going on. It does not purport to authorize banishment on a negative finding, and no such authority can properly be implied. This conclusion is reinforced by comparison of the new drug provision analyzed above with the elaborate provisions of the Act specifically concerned with food. Sections 302, 303 and 304 authorize the Administrator to bring civil and criminal actions based on the substantive provisions of Sections 402 and 403 to banish from the market foods which are likely to injure consumer health or likely to cause deception of consumers.* It is significant that Congress required the Administrator in these cases to prove affirmatively at least a likelihood of injury or deception. He could not succeed in a court action merely because a defendant had failed to prove a likelihood of "no injury" or a lack of deception, even where he was acting under provisions primarily and specifically concerned with deception and safety. See *United States* v. *Lexington Mill & Elevator Co.*, 232 U. S. 399 (1914).

These are the basic statutory provisions authorizing the Administrator to act with respect to foods. They authorize banishment from the food supply only by a court. They require an affirmative finding that the banned product is likely to harm or deceive.

In addition, Congress adopted the food standard provision of Section 401, to implement the Administrator's power to bring court actions against food producers who sold things which were not what they purported to be. The power to establish standards of identity was granted primarily to protect the public against deception and was not

*Technically, of course, actions are brought in the name of the United States by the Department of Justice.

addressed primarily to food safety. The section speaks of promoting "honesty" and "fair dealing" and its legislative history shows clearly Congress' primary concern with the economic integrity of food.* But even if safety considerations were relevant under Section 401, that Section does not authorize the Administrator to act on a negative finding any more than do the provisions which specifically authorize court action against unsafe or deceptive foods. As we have shown, where the Congress intended to authorize administrative action on the basis of a negative finding, as in the new drug provision *adopted at the same time as part of the same statute,* it clearly provided for that action. Only an unwarranted construction of Section 401 could authorize

---

*The House Committee Report on Section 401 was as follows:

"Section 401 provides much needed authority for the establishment of definitions and standards of identity and reasonable standards of quality and fill of container for food. One great weakness in the present food and drug law is the absence of authoritative definitions and standards of identity except in the case of butter and some canned foods. The Government repeatedly has had difficulty in holding such articles as commercial jams and preserves and many other foods to the time-honored standards employed by housewives and reputable manufacturers. The housewife makes preserves by using equal parts of fruit and sugar. The fruit is the expensive ingredient, and there has been a tendency on the part of some manufacturers to use less and less fruit and more sugar.

"The Government has recently lost several cases where such stretching in fruit was involved because the courts held the well-established standard of the home, followed also by the great bulk of manufacturers, is not legally binding under existing law. By authorizing the establishment of definitions and standards of identity this bill meets the demands of legitimate industy and will effectively prevent the chiseling operations of the small minority of manufacturers, will in many cases expand the market for agricultural products, particularly for fruits, and finally will insure fair dealing in the interest of the consumer."

H. R. Rep. 2139, 75th Cong., 2d Sess. (1938).

the Administrator to banish an ingredient on a negative administrative finding about safety, when he cannot even get a Court to act on the basis of such findings under the sections of the Act dealing primarily with food safety or the sections dealing primarily with deception in food.

Analysis of the statutory scheme reveals that where Congress meant the Administrator to have the authority to exclude an item from commerce on a negative finding, it considered the question with great care and specifically gave him that authority. The absence of that authority in connection with the food standards provision is conspicuous. This Court has often indicated that the absence, in one section of a statute, of authority granted in another section enacted at the same time as part of the same law, indicates a Congressional intent not to grant the claimed authority in the silent section. *Cf. Addison* v. *Holly Hill Fruit Products, Inc.*, 322 U. S. 607 (1944); *Crane* v. *Commissioner*, 331 U. S. 1 (1947). If the Administrator believes that the statute should be amended, "he is authorized to call the attention of Congress to the fact," as he has, in fact, done with respect to new chemical food ingredients.* *Cf. F. P. C.* v. *Panhandle Eastern Pipe Line*

---

*Congress has had and now has under active consideration bills supported by the Administrator which would extend to him the power to exclude new chemical food ingredients and chemical additives on the basis of a negative finding similar to the power which he enjoys over new drugs. H. R. 2245, 83rd Cong., 1st Sess. (January 29, 1953), *infra*, p. 19a. A similar bill, H. R. 3257, 82d Cong., 1st Sess. (March 15, 1951), was introduced in the 82d Congress. The Select Committee to Investigate the Use of Chemicals in Food Products recommended the adoption of legislation to require testing and approval of chemical additives to foods before marketing, modeled on the procedure now employed with respect to new drugs. H. R. Rep. No. 2356, 82d Cong., 2d Sess. (June 30, 1952). This Commit-

Co., 337 U. S. 498, 515-516 and n. 25 (1949). "It is no warrant for extending a statute that experience may disclose that it should have been made more comprehensive," *Addison* v. *Holly Hill Fruit Products, Inc., supra,* at 617; *cf. United States* v. *Cardiff*, 344 U. S. 174, 175-6 (1952). In approving the Administrator's attempt to graft on to the food standards provision a power not given by Congress to exclude food ingredients on a negative finding, the Court of Appeals has rendered a decision which should be reviewed by this Court.

Instead of meeting these arguments and analyzing this novel problem of statutory construction,* the Court of Appeals rested its decision primarily upon this Court's opinion in *Federal Security Administrator* v. *Quaker Oats Co.*, 318

---

tee recommendation responded, in part at least, to a request for legislation by the Commissioner of the Food and Drug Administration. *Hearings Before the House Select Committee to Investigate the Use of Chemicals in Food Products*, 81st Cong., 2d Sess. 33-34 (1950).

An earlier report of the same Committee suggests that Section 401 already "gives the Administrator the power to determine in advance of its use whether a chemical proposed for use in a standardized food is safe." H. R. Rep. 3254, 81st Cong., 2d Sess. 10 (1951). This suggestion, however, gives no support to the assertion that the Administrator may resort to a negative finding to eliminate an established ingredient from a food standard.

*To avoid answering our argument that the Administrator lacks power to exclude a food ingredient on the basis of a negative finding, the Court of Appeals attempted to invade the Administrator's province of finding and weighing facts by implying that the record contains sufficient evidence to justify an affirmative finding of possible harm (R. 3292). But the Administrator did not so find and, in an honest exercise of his office, presumably could not so find. Moreover, this Court has refused to consider whether administrative action could be upheld on another ground if the ground advanced by the Administrator does not support his action. *S. E. C.* v. *Chenery Corp.*, 318 U. S. 80 (1943). See also *Saginaw Broadcasting Co.* v. *F. C. C.*, 96 F. 2d 554, 560-61 (D. C. Cir. 1938), *cert. den.*, 305 U. S. 613 (1938).

U. S. 218 (1943). We respectfully submit that this reliance was misplaced. In the *Quaker Oats* case the Administrator *affirmatively* found that the use of the farina product there at issue "*would tend* to confuse and mislead consumers." *Id.* at 220 (Emphasis supplied). This Court did not approve expulsion from the market because Quaker Oats failed to establish that there was no likelihood that its product would confuse and mislead consumers.

The Court of Appeals also relied heavily upon a distinction between "regulations of legislative type" and a "civil action for damages to be decided in accordance with the preponderance of the evidence" (R. 3295-3296). That distinction—or the distinction between "rule-making" and "adjudication"—does not give an answer to the instant question of statutory power; it merely evades the issue. Even assuming that the proceedings before the Administrator were completely "legislative" in character—an assumption which ignores most of the relevant indicia (including statutory provision for a hearing, cross-examination, detailed findings, and a high degree of judicial review)—the Food, Drug, and Cosmetic Act prescribes standards of fact-finding and standards of review for this type of proceeding which we contend have been ignored. The Administrator's negative finding, as approved by the Court of Appeals, goes beyond the authority granted by the statute. It frustrates the command of Section 701(e) of the Act. It banishes our product from its established market without the benefit of "detailed findings," subject to effective judicial review.

The Court of Appeals, by what we think is erroneous statutory construction, has approved extension of the Administrator's powers far beyond the limits of what Congress

intended. As a result the Court has permitted the Administrator to legislate where Congress did not intend to act and has not yet acted.

II.

The decision of the Court below that a crucial finding of fact made by the Administrator was sustainable even though unsupported by any evidence of record is in conflict with applicable decisions of this Court.

In order to justify his disparate treatment of the Atlas product and the competing mono- and diglycerides, it was necessary for the Administrator to make findings which drew a distinction between the two classes of products.

In his tentative 1950 Order the Administrator proposed to permit the use of mono- and diglycerides at a level of not more than 25% of the shortening content of bread without making any finding as to whether or not they were deceptive (R. 16). The Administrator based his tentative decision to exclude the Atlas products in part on a finding that they served to "soften" bread, an effect which he found to be "deceptive" (R. 8-11). We pointed out in our motion to re-open the record (R. 57-59), and in offers of proof submitted in support thereof (R. 157-161, 171-267), that mono- and diglycerides at the permitted 25% level have the same "softening" effect as Myrj 45; and consequently, if "deception" of consumers was thought to result from the use of Myrj 45 in bread, the same "deception" must result from use of the competing mono- and diglycerides.

The Administrator acknowledged the force of this argument by finding in his final order that use of mono- and diglycerides at "excessive" levels (presumably the 25% level permitted by his proposed order) would produce the

same "softening" effect as Myrj 45 (R. 460). Since the "softening" effect of Myrj 45 was labeled as "deceptive", the Administrator found it necessary to set a "non-deceptive" level of use for the mono- and diglycerides, in terms of a percentage of the shortening content of bread. The level chosen—twenty percent of the shortening content of bread—was designed, as the Court below stated, to "preserve the advantages of shortening while minimizing the dangers of deceptive softening" (R. 3295). We have been able to find but one series of references in the portions of the record cited by the Administrator to a twenty percent level of mono- and diglycerides in shortening as non-deceptive (R. 693-694, 706). That reference is in the testimony of one Bradley. His testimony was modified on cross-examination and ultimately abandoned on redirect (R. 707-709).

In sustaining the Administrator's determination of a non-deceptive level of use for mono- and diglycerides, the Court below was unable to state and did not state that the determination was supported by substantial evidence. In fact, it was supported by no evidence. The Court below was able to say only that "we are not persuaded that the Administrator acted arbitrarily . . . in his determination of an unobjectionable proportion of glycerides" (R. 3295).*

---

*The language in the opinion of the Court below on this point may not be entirely clear on first reading. The Court was dealing with two questions at the same time: (1) whether the distinction drawn by the Administrator between the function of the Atlas products and the function of the mono- and diglycerides is supported by substantial evidence, and (2) whether the Administrator's finding as to a "non-deceptive" level of mono- and diglycerides is sustainable. The Court stated its conclusion on both these questions in the same sentence. It concluded that the functional distinction was supported by evidence; but it could only conclude that the setting of a non-deceptive level for

The necessary inference is that the matter was one on which the Administrator's opinion was sufficient, regardless of whether there was any evidence of record to support it. Yet, it was only on the basis of this finding of fact that the Administrator was able to say with any plausibility that there was a difference between the Atlas products and the mono- and diglycerides on the issue of deception. This finding was vital to the distinction drawn; without it, the distinction was an illegal discrimination.* The holding that there need be no evidence to support a finding of fact, the validity of which goes to the root of the administrative action being reviewed, runs directly counter to many forcible expressions by this Court. See, *e. g., S. E. C.* v. *Chenery Corp.,* 318 U. S. 80 (1943); *Universal Camera Corp.* v. *N. L. R. B.,* 340 U. S. 474 (1951). See also *Cream Wipt Food Products Co.* v. *Federal Security Administrator,* 187 F. 2d 789 (3d Cir. 1951).

---

mono- and diglycerides was not an arbitrary exercise of the Administrator's judgment.

> "While the description and exposition of the 'shortening' effect of the glycerides in the record is less than one might desire for clarity, we think that at least there is substantial evidence that these additives make bread 'tenderer to the bite'. Moreover, in recognition of this distinction, *the Administrator permitted the use of glycerides only at a stated level which in his judgment would preserve the advantages of shortening while minimizing the dangers of deceptive softening.* Petitioners insist that the evidence relied upon to support this distinction does not do so when correctly analyzed. While this interpretation is arguable, *we are not persuaded that the Administrator acted arbitrarily* either in his contrary interpretation of the evidence or *in his determination of an unobjectionable proportion of glycerides*" (R. 3295, emphasis supplied).

*The emphasis in the record on the question of deception (R. 460-461, 466) shows that if the Administrator could not establish a non-deceptive level for mono- and diglycerides, he could not and would not have admitted them and excluded Myrj 45, merely because of claims that mono- and diglycerides enhance shortening.

III.

Contrary to the plain language of the Food, Drug, and Cosmetic Act, as well as prior decisions of this Court, the Court of Appeals denied an application for leave to adduce additional evidence without independently determining the materiality of that evidence.

Section 701(f)(2) of the Federal Food, Drug, and Cosmetic Act provides that:

> "If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary [now the Administrator], the court may order such additional evidence . . . to be taken before the [Administrator] . . ."

The application contemplated by the statute is addressed to the discretion of the Court and *not* to that of the administrative agency. This provision places upon the Court of Appeals the duty to determine *itself, de novo,* whether or not the additional evidence sought to be adduced is material and whether or not there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Administrator. This statutory duty differs from that of merely determining whether or not the Administrator abused *his* discretion in refusing to receive the additional evidence—a lesser duty of review which exists even in the absence of statute. See *Atchison, T. & S. F. Ry. Co.* v. *United States,* 284 U. S. 248 (1932); *I. C. C.* v. *City of Jersey City,* 322 U. S. 503 (1944). Therefore, as this

Court has held in *N. L. R. B.* v. *Indiana & Michigan Electric Co.*, 318 U. S. 916 (1943), interpreting an identical provision of the National Labor Relations Act, the Court of Appeals must *itself* review the nature of the evidence offered and determine, *itself*, whether such evidence is *material*. See also *Southport Petroleum Co.* v. *N. L. R. B.*, 315 U. S. 100, 104 (1942); *N. L. R. B.* v. *Mexia Textile Mills*, 339 U. S. 563, 569 (1950); *cf. N. L. R. B.* v. *Donnelly Garment Co.*, 330 U. S. 219, 233-236 (1947).

The additional evidence which we sought to have introduced in a reopened hearing included extensive experimental work on the safety of Myrj 45 carried out by the Food and Drug Administration's scientists subsequent to the close of the hearings on September 20, 1949 (R. 37-40, 347-350, 451-455). The Administrator denied our motions when he issued his final order on May 12, 1952 (R. 456-457, 476-484).

In our petition for review, we applied to the Court of Appeals pursuant to Section 701(f)(2) for leave to adduce additional evidence, including evidence of the experimental work conducted on our product by the Administrator's staff (R. 3249). Since the status, methods and results of this experimental work (the elements which would determine their materiality as additional evidence) were not within our direct knowledge, but on the contrary, were peculiarly within the Administrator's knowledge and control, we requested specific information from him concerning them.* He had previously considered these tests sufficiently important to submit information about them to the National Research Council, to aid that body in its considera-

*Reply brief for Petitioner in Court of Appeals, pages 5a-6a. Certified copy lodged with the Clerk of this Court.

tion of problems relating to the use of chemicals in foods. But the Administrator refused us access to the same information on the ground that we might present it to the Court.*

The Administrator's continued refusal of our requests for information about the status of the testing program conducted by his own expert assistants effectively blocked the presentation of the results of these tests to the Court of Appeals.

In the Court of Appeals the Government explained its failure to reopen the record to receive the evidence of the new tests as follows:

> "The argument about alleged tests made by the Food and Drug Administration has considerable superficial appeal. But it must be remembered that the Atlas allegations are based on speculation. *As a matter of fact, after this petition for review was filed, Atlas sought to interrogate the Administrator about the tests.* The Company was told that no tests have been completed that change the picture presented by the existing record. Before the final order issued, the Administrator had before him the Atlas allegation that results of Food and Drug Administration tests were extant. Nevertheless, he denied the motion. *Actually, the Administrator asked the Food and Drug Administration if it had any results of tests that would settle the question of safety. He was informed that the Administration had no such data. The final order was promulgated on the record"* Government's Brief in the Court of Appeals in No. 10,765, pp. 71-72 (emphasis supplied).

On the strength of this representation by the Administrator in his brief, the Court of Appeals concluded that

*Reply brief, page 8a.

"the most recent governmental research is not and does not purport to be decisive as to the safety of the Atlas products and thus did not warrant re-opening the record" (R. 3297). This decision as to the materiality of evidence on the hearsay representation of a party, without independent examination of the evidence, was clearly wrong. At the very least, the Court of Appeals should have required the Administrator to furnish to the Court and to Atlas the evidentiary record of the tests on Myrj 45 conducted in his own laboratories, so that the Court could determine for itself whether this evidence was sufficiently "material" to justify the re-opening of the record.

To the extent that the Court below failed to make an independent evaluation of the additional evidence which we proffered, its decision narrows judicial review of orders issued by several administrative agencies, under a variety of regulatory statutes, since these statutes include provisions as to the taking of additional evidence substantially identical with Section 701(f)(2) of he Food, Drug and Cosmetic Act.*

If the rule of the *Indiana & Michigan Electric Co.* case, *supra,* is to be narrowed, it should not be done *sub silentio* by an intermediate appellate court, but after careful con-

---

*Section 5(c) of the Federal Trade Commission Act, 38 Stat. 717, 720 (1914), 15 U. S. C. 45(c); Section 9(a) of the Securities Act of 1933, 48 Stat. 74, 80 (1933), 15 U. S. C. 77i(a); Section 25(a) of the Securities Exchange Act of 1934, 48 Stat. 881, 902 (1934), 15 U. S. C. 78y(a); Section 24(a) of the Public Utility Act of 1935, 49 Stat. 803, 834 (1935), 15 U. S. C. 79(x)(a); Section 322(a) of the Trust Indenture Act of 1939, 53 Stat. 1149, 1175 (1939), 15 U. S. C. 77 vvv(a); Section 42(a) of the Investment Company Act of 1940, 54 Stat. 789, 844 (1940), 15 U. S. C. 80a-42(a); Section 10(e) of the Labor Management Relations Act of 1947, 61 Stat. 136, 148 (1947), 29 U. S. C. 160(e); Section 7(c) of the Judicial Review Act of 1950, 64 Stat. 1129, 1131 (1950), 5 U. S. C. 1037(c).

sideration by this Court, in the light of its effect on a broad area of federal administrative law.

CONCLUSION

The petitioner prays that the writ be granted.

OSCAR COX,
1210 18th Street, N. W.,
Washington 6, D. C.
Attorney for Petitioner.

C. C. GAMMONS,
KENNETH E. MULFORD,
ROGER R. HORTON,
Delaware Trust Co. Bldg.,
Wilmington, Delaware.

EZEKIEL G. STODDARD,
LLOYD N. CUTLER,
LOUIS F. OBERDORFER,
HERBERT L. PACKER,
WILLIAM R. PERLIK,
1210 18th Street, N. W.,
Washington 6, D. C.
Of Counsel.

APPENDIX A

Applicable Provisions of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 *et seq.*, 21 U. S. C. 321(p), 331(a)(b) and (c), 332, 333(a), 334(a) and (d), 341, 342, 343, 346, 351(a), 352(a) and (b), 355, 371.

* * *

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

* * *

["New Drug"]

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

* * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

* * *

INJUNCTION PROCEEDINGS

SEC. 302. (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes", approved October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 381), to restrain violations of section 301, except paragraphs (e), (f), (h), (i), and (j).

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 387).

PENALTIES

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

* * *

SEIZURE

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, [or while held for sale (whether or not the first sale) after shipment in interstate commerce]* or which may not, under the provisions of sections 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found:

Provided, however, That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations, shall not apply

(1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or

---

*Phrase in brackets added by 62 Stat. 582 (1948).

(2) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. . . .

* * *

(d) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States . . .

* * *

CHAPTER IV—FOOD

Definitions and Standards for Food

Sec. 401. Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container:

Provided, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the pre-

scribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or

(2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; or

(3) if it consists in whole or in art of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) if any substance has been substituted wholly or in part therefor; or

(3) if damage or inferiority has been concealed in any manner; or

(4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406:

Provided, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum and pectin:

Provided, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

(e) If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless its bears a label containing

(1) the name and place of business of the manufacturer, packer, or distributor; and

(2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count:

Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the

label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless

(1) it conforms to such definition and standard, and

(2) its label bears the name of the food specified in the definition and standard, and insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears

(1) the common or usual name of the food, if any there be, and

(2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings,

other than those sold as such, may be designated as spices, flavorings, and colorings without naming each:

Provided, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact:

Provided, That to the extent that compliance with the rerequirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

* * *

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 406. (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402(a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds

necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.

* * *

CHAPTER V—DRUGS AND DEVICES

Adulterated Drugs and Devices

Sec. 501. A drug or device shall be deemed to be adulterated—

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or

(2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or

(3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious sub-

stance which may render the contents injurious to health; or

(4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 504.

* * *

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing

(1) the name and place of business of the manufacturer, packer, or distributor; and

(2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count:

Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

* * *

NEW DRUGS

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of

subsection (a). Such person shall submit to the Secretary as a part of the application

(1) full reports of investigations which have been made to show whether or not such drug is safe for use;

(2) a full list of the articles used as components of such drug;

(3) a full statement of the composition of such drug;

(4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

(5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and

(6) specimens of the labeling proposed to be used for such drug.

(c) An application provided for in subsection (b) shall become effective on the sixtieth day after the filing thereof unless prior to such day the Secretary by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred and eighty days after the filing thereof) as the Secretary deems necessary to enable him to study and investigate the application.

(d) If the Secretary finds, after due notice to the applicant and giving him an opportunity for a hearing, that

(1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof;

(2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;

(3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or

(4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(e) The effectiveness of an application with respect to any drug shall, after due notice and opportunity for hearing to the applicant, by order of the Secretary be suspended if the Secretary finds

(1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective, or

(2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

(f) An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever the Secretary finds that the facts so require.

(g) Orders of the Secretary issued under this section shall be served

(1) in person by any officer or employee of the department designated by the Secretary or

(2) by mailing the order by registered mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing to permit the application to become effective, or suspending the effectiveness of the application. Such appeal shall be taken by filing in the district court of the United States within any district wherein such applicant resides or has his principal place of business, or in the District Court of the United States for the District of Columbia, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the record upon which the order complained of was entered. Upon the filing of such transcript such court shall have exclusive jurisdiction to affirm or set aside such order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment and decree of the court affirming or setting aside any such order of the Secretary shall be final, subject to review as provided in sections 128, 239, and 240 of the Judicial

Code, as amended (U. S. C., 1934 ed., title 28, secs. 225, 346, and 347), and in section 7, as amended, of the Act entitled "An Act to establish a Court of Appeals for the District of Columbia," approved February 9, 1893 (D. C. Code, title 18, sec. 26). The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) The Secretary shall promulgate regulations for exempting from the operation of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs.

* * *

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) The Secretary of the Treasury and the Secretary of Agriculture shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Agriculture shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be

contained in other laws of the United States and regulations promulgated thereunder.

(e) The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: 401, 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504, and 604. The Secretary shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Secretary, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Secretary shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Secretary finds that emergency conditions exist necessitating an earlier effective date, then the Secretary shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Secretary shall specify therein to meet the emergency.

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such

order. The summons and petition may be served at any place in the United States. The Secretary, promptly upon service of the summons and petition, shall certify and file in the court the transcript of the proceedings and the record on which the Secretary based his order.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) The Court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

* * *

Text of H. R. 2245, 83d Congress, 1st Sess., January 29, 1953.

A BILL

To amend the Federal Food, Drug, and Cosmetic Act by providing for the regulation of chemical additives in food.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 201 of the Federal Food, Drug, and Cosmetic Act is amended by adding the following paragraph:

"(q) The term 'chemical additive' means any substance (including products resulting from changes in such substance after use) which (1) is intended for use (A) as a food, or (B) to preserve or alter any food or any characteristic of any food, or (C) as a pesticide or for any other purpose in producing, processing, packing, transporting, wrapping or holding food if such use if likely to result in the contamination of the food; and (2) is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of such substances, as having been adequately tested to show that it is not poisonous or deleterious, or is a poisonous or deleterious substance which is not generally recognized among such experts as having been adequately tested to show that it is safe for an intended use described in this paragraph."

SEC. 2. Section 407 of such Act shall hereafter be designated as section 408.

SEC. 3. Section 301 of such Act is amended by changing "404 or 505" in subsection (d) to "404, 407, or 505"; and "404, 505, 506, 507, or 704" in subsection (j) to "404, 407, 505, 506, 507, or 704".

SEC. 4. Section 304 of such Act is amended by changing "404 or 505" in subsections (a) and (d) to "404, 407, or 505".

SEC. 5. Section 402 (a) of such Act is amended by changing the period at the end to a semicolon and adding: "or (7) if it bears or contains any chemical additive, unless the use of such chemical additive in the quantity present in or on such food has been approved pursuant to section 407."

SEC. 6. The following section shall be added to chapter IV of such Act:

"CHEMICAL ADDITIVES

"SEC. 407. (a) No person shall introduce or deliver for introduction into interstate commerce any chemical additive, unless the use of such chemical additive has been approved pursuant to subsection (d) or (e).

"(b) Any person may file with the Administrator a request for the issuance of an order approving the use of a chemical additive. There shall be submitted to the Administrator as a part of the request (1) reports of investigations which have been made to determine the acute and chronic toxicity and other potentiality for harm of the chemical additive; (2) a statement of the composition of the chemical additive; (3) a description of methods of analysis for the quantitative determination of the chemical additive in or on food, including animal or plant tissues if stored therein; (4) such samples of the chemical additive as the Administrator may require; (5) all directions, recommendations and suggestions proposed for the use of the chemical additive; and (6) if the chemical additive is a poisonous or deleterious substance (A) a statement showing that the chemical additive is required in the production of food, (B) reports of investigations which have been made to show the quantities of the chemical additive, if any, remaining in or on the food, and (C) a description of adequate methods of removal of excessive quantities of the chemical additive remaining in or on the food.

"(c) After the use of a chemical additive has been approved, the applicant may file a supplemental request set-

ting forth any proposed change in the directions, recommendations and suggestions for the use of the chemical additive or in any other information in the original request.

"(d) Unless the Administrator issues a notice of hearing pursuant to subsection (e) prior to the sixtieth day after the date on which a request or supplemental request is filed, the request or supplemental request shall be deemed to have been approved on said sixtieth day for the uses specified; but the Administrator may issue an order approving the request or supplemental request at an earlier date or may postpone the date on which the request or supplemental request shall be deemed to have been approved until such time (not more than one hundred and eighty days after it has been filed) as the Administrator deems necessary to enable him to conduct the necessary study and investigation.

"(e) Unless a request or supplemental request is approved as provided in subsection (d), the Administrator shall give the applicant an opportunity for a hearing for the purpose of determining whether an order shall be issued approving the request or supplemental request. As soon as practicable after completion of the hearing, the Administrator shall notify the applicant of his action in approving or refusing to approve the request or supplemental request. If the Administrator finds that (1) the investigations, reports of which are required to be submitted to him pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show that the chemical additive is not poisonous or deleterious, or if it is, that it is safe and required for its intended use; or (2) the results of such tests show that the chemical additive is poisonous or deleterious, and that it is unsafe or not required for such use or do not show that it is safe and required for such use; or (3) the methods of analysis for the quantitative determination of such chemical additive in or on food, including animal and plant tissues if stored therein, or the methods

of removal of excessive portions, are inaccurate or otherwise inadequate; or (4) he has insufficient information to determine whether the chemical additive is poisonous or deleterious, or if it is, whether it is safe and required for such use, he shall refuse to approve the request or supplemental request. In determining whether to issue an order approving a request or supplemental request for the use of a chemical additive and the quantity of such chemical additive to be permitted in or on any food, the Administrator shall take into account the extent to which such substance is required in or on such food and the other ways in which the consumer may be affected by the same substance or other substances. The Administrator shall make his order, and any order issued under subsection (f), only after a review of the whole record and in accordance with the reliable, probative and substantial evidence, and in any such order shall make detailed findings of the facts on which he based his order. Such orders shall be subject to judicial review in accordance with the provisions of section 701 (f).

"(f) After notice to the applicant and affording him an opportunity for a hearing, the Administrator may issue an order suspending the approval of a request or supplemental request with respect to a chemical additive if he finds that (1) experience in the use of the chemical additive, tests by new methods, or tests by methods not deemed reasonably applicable when the request or supplemental request was approved, show that the chemical additive is unsafe for any use upon the basis of which the request or supplemental request was approved, or (2) the request or any supplemental request contains any untrue statement of a material fact. The applicant may at any time thereafter request an order terminating the suspension and the Administrator, if reasonable grounds therefor are shown, shall make a prompt investigation and afford the applicant an opportunity for a hearing. The Administrator shall terminate the suspension if he finds that adequate measures have been taken to com-

ply with and maintain the provisions of the request or supplemental request.

"(g) The Administrator shall promulgate regulations exempting from the operation of this section chemical additives intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of such chemical additives."

SEC. 7. This statute shall take effect six months after the date of its enactment.

INDEX

	Page
Opinion below	1
Jurisdiction	2
Questions presented	2
Statute involved	4
Statement	5
Argument	18
Conclusion	28

CITATIONS

Cases:

American Airlines, et al. v. *Civil Aeronautics Board*, 192 F. 2d 417	24
Anniston Mfg. Co. v. *Davis*, 301 U.S. 337	21
Buttfield v. *Stranahan*, 192 U.S. 470	20
Federal Security Administrator v. *Quaker Oats Company*, 318 U.S. 218	19, 23, 24
Interstate Commerce Commission v. *Jersey City*, 322 U.S. 503	27
Lichter v. *United States*, 334 U.S. 742	20
Market Street Ry. Co. v. *Railroad Commission*, 324 U.S. 548	25
National Labor Relations Board v. *Donnelly Garment Co.*, 330 U.S. 219	28
National Labor Relations Board v. *Pittsburgh S.S. Co.*, 340 U.S. 498	25
62 Cases of Jam v. *United States*, 340 U.S. 593	19
Universal Camera Corp. v. *National Labor Relations Board*, 340 U.S. 474	25, 26
Wong Yang Sung v. *McGrath*, 339 U.S. 33	22

Statutes:

Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040; 21 U.S.C. 301:	
Sec. 401 (21 U.S.C. 341)	4, 20
Sec. 402(a), 21 U.S.C. 342(a)	23
Sec. 402(b), 21 U.S.C. 342(b)	23
Sec. 403(g) [21 U.S.C. 343(g)]	5
Sec. 505, 21 U.S.C. 355	22
Sec. 701(e), 21 U.S.C. 371(e)	4
Sec. 701(f), 21 U.S.C. 371(f)	4, 26

Misc.:

Dunn, *Federal Food, Drug, and Cosmetic Act, A Statement of Its Legislative Record*, 1316-1327	22
H. Rep. No. 2139, 75th Cong., 3d Sess., 2	23
H. Rep. No. 2356, 82d Cong., 2d Sess., 24	22
S. Res. 194, 75th Cong., 2d Sess., Dunn, pp. 1316-1327	22

In the Supreme Court of the United States

OCTOBER TERM, 1952

No. 584

GLYCO PRODUCTS CO., INC., PETITIONER

v.

FEDERAL SECURITY ADMINISTRATOR

No. 610

ATLAS POWDER COMPANY, A CORPORATION, PETITIONER

v.

OSCAR R. EWING, FEDERAL SECURITY ADMINISTRATOR

ON PETITIONS FOR WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINION BELOW

The opinion of the Court of Appeals (Glyco R. 757 and Atlas R. 3283) is reported at 201 F. 2d 347. The administrative order under review (Glyco R.

700-746 and Atlas R. 458-475) was published at 17 F. R. 4453. Respondent's memorandum denying Atlas Powder Company's motion to reopen the record (Atlas R. 476-484) was published at 17 F. R. 4467.

JURISDICTION

The judgment of the Court of Appeals was entered December 22, 1952 (Glyco R. 773 and Atlas R. 3299). Atlas Powder Company's petition for rehearing was denied January 14, 1953 (Atlas R. 3299). Glyco Products Company filed its petition for a writ of certiorari on February 4, 1953. Atlas Powder Company filed its petition on February 17, 1953. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1) and Section 701(f)(4) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 1055, 21 U.S.C. 371(f)(4).

QUESTIONS PRESENTED

1. Whether the Federal Security Administrator, in establishing a standard of identity for bread to "promote honesty and fair dealing in the interest of consumers", was required to authorize, and was without authority to forbid, the use of polyoxyethylene monostearate, a synthetic chemical bread softener, which he found on substantial evidence—

(a) contains residues of known poisonous glycols;

(b) is a reaction product of variable and uncertain chemical composition, not a chemical entity, containing some polyoxyethylene glycol esters of low and high molecular weights

known to be poisonous to experimental animals;

(c) has no history of long use in food from which its safety could be appraised;

(d) has been improperly and insufficiently tested by pharmacological and related methods to establish scientifically whether it is safe for the use proposed;

(e) has an unknown metabolic fate in the animal and human body after ingestion;

(f) may be responsible for causing urinary calculi observed in bladders taken from experimental animals;

(g) may increase the susceptibility of animals to infectious disease organisms ingested with food; and

(h) serves no useful purpose in bread, but, on the contrary, gives bread a deceptive artifical softness enabling bakers to sell old bread as fresh bread.

2. Whether, despite such evidence and findings as a basis for the exclusion of polyoxyethylene monostearate, the Administrator nevertheless was compelled to permit its use because he permitted use of another class of surface active agents (mono- and diglycerides) which he found significantly different, in that the use of the latter could be so limited in amounts as to avoid deceptive bread softening while preserving their advantages as shortening.

3. Whether the Administrator, in the first instance, and the Court of Appeals, on review, abused their discretion in refusing to reopen the record

when each concluded independently that the several tenders of alleged new evidence by Atlas, including a tender of evidence said by Atlas to be in the Administrator's possession, would not change the result because all such evidence was incomplete and indecisive on the safety issue.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040; 21 U.S.C. 301 *et seq.*, in pertinent part, provides:

> Sec. 401 [21 U.S.C. 341]. Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity * * * In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. * * *

The regulations may be promulgated only after public proceedings and must be based on a record made at a hearing. Sec. 701(e), 21 U.S.C. 371(e). Judicial review of the regulations is permitted under Section 701(f), 21 U.S.C. 371(f).

After a standard of identity has been established, a food that fails to comply is declared to be misbranded.

> Sec. 403 [21 U.S.C. 343]. A food shall be deemed to be misbranded—
>
> (g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavorings, and coloring) present in such food.

STATEMENT

Petitioners are attacking a rule-making order of the Federal Security Administrator by which he established a standard of identity for bread. They will be adversely affected because in the future the order will not permit bakers—petitioners' customers—to use polyoxyethylene monostearate as a bread softener.

The administrative proceeding, after an interruption due to the war, was reopened in 1948 for taking evidence of new developments in baking technology (Atlas R. 1-4). The principal of these was the introduction in early 1947 of polyoxyethylene monostearate to make bread softer to the touch over a period of days and thus to appeal to

the large segment of the public which judges bread freshness by squeezing the wrapped loaf.

The reopened hearing lasted 116 days, ending September 20, 1949. More than 160 witnesses testified; the record grew to 17,000 pages; more than 500 exhibits were received Most of this evidence related to the chemical bread softeners.

Atlas Powder Company produces polyoxyethylene monostearate—trade name Myrj 45—by the direct reaction of ethylene oxide with commercial stearic acid in a theoretical proportion of eight molecules of ethylene oxide to one molecule of stearic acid (Atlas R. 3205). The competing Glyco product—trade name Sta-Soft—is produced by first reacting ethylene oxide with water, ethylene glycol, or diethylene glycol to form polyoxyethylene glycol which is then reacted with stearic acid (Atlas R. 1394-1395, 1447, 1451, 1500) . Neither Myrj 45 nor Sta-Soft is a chemical entity (Atlas R. 729, 1538-1539). The products, despite the different methods of production, are substantially alike (Atlas R. 1463, 1516, 1824, 2057-2058, 2059, 3205-3206, Ex. 95).

Before the introduction of the chemical softeners into the bread supply, polyoxyethylene glycols had been used as commercial chemicals in plastics, insecticides, antifreezes, polishes, etc., but were not used in foods (Ex. 100, pp. 2, 4, 10, Ex. 102, pp. 12-15, 67-78). In late 1946 or early 1947, cereal chemists employed by R. T. Vanderbilt Company discovered that polyoxyethylene monostearate had a softening effect on bread (Atlas R. 725-726,

2855, Ex. 58).[1] They promptly offered it to bakers for commercial use (Atlas R. 2855, 2882).

The American Institute of Baking, the scientific and educational organization of the industry (Atlas R. 532), soon thereafter issued a bulletin cautioning bakers against using the chemical (Atlas R. 697-698). Bakers were told that the active ingredient belonged to a group of chemical compounds, some of which are notoriously poisonous, and that satisfactory evidence of harmlessness had not been made available.[2] The Food and Drug Administration also questioned the safety of the softener (Atlas R. 3083). Nevertheless, many bakers began to use it (Atlas R. 692), largely because of competition from softer loaves (Atlas R. 3000, 3005, 3011, 3016, 3036, 3063, 3084, 3087).

The notice of reopening the hearing, published in October 1948, included a proposed regulation which did not permit use of the softeners. At the hearing, neither the American Bakers Association, composed primarily of wholesale bakers, nor the Retail Bakers Association advocated or presented evidence to support their use. The burden of establishing that use of polyoxyethylene monostearate in bread would be consistent with the promo-

---

[1] Atlas asserts that its product is an emulsifier (No. 610, Pet. 3). Its own witness testified that the Company has never been able to demonstrate whether Myrj 45 functions as an emulsifier (Atlas R. 753). Unlike mono- and diglycerides, its action in bread dough is independent of the shortening used (Atlas R. 674-675, 753).

[2] The only evidence of safety in Atlas' possession at that time was some preliminary tests done by Dr. John C. Krantz, which he admitted were inadequate to justify use of Myrj 45 in bread (Atlas R. 847-848, 3173-3174).

tion of honesty and fair dealing in the interest of consumers thus fell upon Atlas Powder Company and Glyco Products Company, primary manufacturers, and R. T. Vanderbilt Company and C. J. Patterson Company, distributors of Myrj 45 and Sta-Soft.[3] To do this, they undertook to explain the chemical composition of the softener, to prove that polyoxyethylene monostearate[4] serves a useful function in bread, and that its safety had been established through pharmacological testing with small laboratory animals,[5] through experiments to determine its metabolic fate,[6] and by feeding it

---

[3] Under Section 7(c) of the Administrative Procedure Act, 5 U. S. C. 1006 (c), the Food and Drug Administration had the general burden of supporting the regulations. But other parties who were proponents of a different regulation from that proposed also had a burden to maintain for that purpose. Sen. Rep. No. 752, 79th Cong., 1st Sess. (1945), Administrative Procedure Act, Legislative History, Sen. Doc. No. 248, 79th Cong., 2d Sess., 208 (1944-1946).

[4] Atlas proposed before the Administrator that he permit all of its Spans, Tweens, and Myrjs. Its chief chemist, Dr. Rose, recommended an amendment which would cover its entire line (Atlas R. 711-712, 713-716, 717-720, 723-725). In each group of Spans, Tweens, and Myrjs, a myriad of different compounds was possible (Atlas R. 729-732), including many that had never been studied (Atlas R. 732).

[5] In studying the toxic potential of a substance like polyoxyethylene monostearate, it is standard practice to conduct both acute and long term feeding tests with small laboratory animals. To give the chronic test validity, it is necessary that the experiment be conducted with test animals and control animals. These are selected so as to make the two groups as nearly identical as possible at the start of the test. During the test, the animals' diet and living conditions are identical except that the diet of the test group contains the material being studied. Any differences between the test animals and the controls, theoretically at least, are due to the material under study.

[6] This was a study in which the excretions of test animals and some human patients were examined to determine whether the body promptly eliminated the non-food part of polyoxyethylene monostearate. The compound is about 40% stearic

to a few people under the care of a physician where they could be observed for symptoms of harm.[7]

All of the evidence offered by the proponents was critically cross-examined. Many defects in the safety testing were developed.[8] In addition, Swift & Company and the Institute of Shortening and Edible Oils, Inc., presented two scientists, Dr. Anton J. Carlson, the physiologist, and Dr. Robert S. Harris, M.I.T. nutritionist, both of whom expressed expert opinions that the Atlas and Glyco showing as to safety was inadequate (Atlas R. 2913-2915, 2936, 2951-2962).

Expert witnesses representing the Council on Foods and Nutrition of the American Medical Association (Atlas R. 2832-2850) and the Food and Nutrition Board of the National Research Council (Atlas R. 2900-2901) offered resolutions adopted by these scientific groups urging that the softeners should not be permitted in bread until their safety was shown beyond doubt. The Council on Foods and Nutrition, which had reviewed the Atlas scientific work (Atlas R. 2841-2842), stated (Atlas R. 2845-2846):

> Available knowledge of the possible toxicity of these substances [Atlas products] is fragmentary—particularly is evidence lacking as to chronic toxicity. The employment of these

---

acid, which would be utilized as food and about 60% "polyol", which is non-food.

[7] The longest controlled human feeding test with Myrj 45 lasted about one month (Atlas R. 1212) and only 3 people under any observation at all had taken it for more than 6 months (Atlas R. 1244). The longest feeding was 11 months (Atlas R. 1191).

[8] See for example footnote 12 *infra*, pp. 14-15.

> agents in * * * bread * * * could lead to the ingestion of considerable quantities of these materials of uncertain toxicological action.

As to functional use, there was conflicting evidence whether polyoxyethylene monostearate affected bread softness only or whether it arrested the process of staling (Atlas R. 539, 550, 552-559, 562, 569-570, 735-736, 742, 3082, 3089, Ex. 58), and whether the softener improved or adversely affected bread quality (Atlas R. 537-539, 2785, 2811, 2880, 2903, 2992, 2998-2999, 3005-3006, 3015, 3029, 3037, 3044-3045, 3049, 3053-3054, 3058, 3064).

Practically all of the bakers testified, however, (1) that the public confuses softness with freshness in purchasing bread (Atlas R. 2798-2799, 2807-2808, 2818, 2829, 2899, 2903, 3005, 3012, 3019, 3031, 3038, 3059), (2) that the use of softeners would enable them to leave bread on the retail shelves longer and thus sell old bread as fresh bread (Atlas R. 2084, 2798, 2887, 2895, 3006-3007, 3050, 3056, 3060), and (3) that the softeners would facilitate "bread rolling", i.e., where old bread is taken from one retail outlet and left at another as fresh bread (Atlas R. 2091, 2904-2905, 2994, 3017-3019, 3041, 3045-3046, 3064).

The Administrator issued a tentative order on August 8, 1950 (Atlas R. 5-16), which did not permit polyoxyethylene monostearate or the other Atlas products proposed. Detailed findings of fact were made which, in summary, were that the

bread softeners were deceptive as to the age of bread and that the scientific investigational work had not definitely established their safety.

Atlas Powder Company (Atlas R. 47-108) and Glyco Products Company (Glyco R. 1-23) excepted to the findings and order. Atlas also filed a motion to reopen the record so that it might show that mono- and diglycerides have the same softening effect as polyoxyethylene monostearate and that the evidence available as to safety of the mono- and diglycerides was no more convincing (Atlas R. 24-39). It was argued that because the use of glycerides was permitted Atlas' products likewise should be permitted (See Atlas R. 384).

On February 2, 1951 (Atlas R. 129) Atlas proposed that all available scientific data be submitted to the newly organized Food Protection Committee of the National Research Council for expert appraisal.[9] The proposal stated that "the results would make it possible for the Federal Security Agency to issue a final order based on impartial scientific opinion, as opposed to opinion which may be colored by the bias and interest of individual manufacturers" (Atlas R. 132). All of the data on safety in this record, together with new experiments, were submitted to the Committee by

---

[9] The National Research Council is a highly reputable scientific organization with semi-official status. It represents "the very foremost in scientific thinking in the United States" (Atlas R. 1014). The Food Protection Committee was created by the National Research Council to aid industry and Government in evaluating the pharmacological properties of chemicals which might find their way into foods.

Atlas prior to June 11, 1951 (Atlas R. 144-148). The Food Protection Committee on that date issued a statement finding that the Atlas evidence was insufficient to show safety (Atlas R. 169-170). The Committee, referring to the Atlas products as "esters of non-glycerol alcohols", concluded that the experiments had not been properly planned to delineate the toxic potentials of the products and that knowledge of their metabolic fate and possible toxicological effects was insufficient.

When the results of the Committee's study were unfavorable to the Atlas compounds, Atlas began to file with the Administrator opposing memoranda (Atlas R. 277, 389, 412-435). In addition, it outlined an extensive program of planned research (Atlas R. 284-299) which, it estimated, would be completed by September 1, 1953 (Atlas R. 271, 299).[10]

On May 12, 1952, the Administrator issued the final order (Atlas R. 458-475).

The Administrator found, on the deception issue, (1) that polyoxyethylene monostearate enables bakers to prepare bread that stays softer to squeezing over a period of days, (2) that softness is the only characteristic of freshness affected by the

[10] In a letter dated December 4, 1951, Atlas referred to certain experiments underway in the Food and Drug Administration, contending that they would be completed in the winter of 1951-1952 and results evaluated by the summer of 1952 (Atlas R. 347). It contended that if these tests were favorable to Atlas, the two-year period it had referred to could be cut down (Atlas R. 350). The Food and Drug Administration's tests are still incomplete (Atlas Reply Brief in Court of Appeals, p. 8a).

chemical, (3) that this artificially created softness enables bakers to appeal to consumers who select bread by feel, thinking the softness to be an indication of freshness, and (4) that this has deceived, and does deceive, the purchaser as to the age of the bread and facilitates the undesirable distribution practice of "bread rolling" (Finding 39, Atlas R. 463-466). He found, in conclusion, that consumers will receive no significant benefits from the use of Atlas type bread softeners and may be deceived by them (Finding 42, Atlas R. 472).

On the question of safety, the Administrator found that polyoxyethylene monostearate softeners were first introduced into the bread supply in 1947 (Finding 39, Atlas R. 463-465). They are of variable chemical composition and are known to contain poisonous glycols (Finding 40, Atlas R. 467-468).[11] The laboratory animal work reported showed injuries when the materials were fed in amounts of 10% or more of the diet, but when lesser amounts were fed the evidence of injury was not clear. The Administrator found fundamental defects in the animal experiments, which he specified. Only one

---

[11] It was clear that the softeners contain small residues of ethylene and diethylene glycol (Atlas R. 1400, 1402, 1406, 1428, 1434, 1442, 1502, 1507, 1529, 1611, 1616-1617, 1663-1673a, 1953, 2019, Ex. 97 and 99), chemicals known to have significant chronic toxicity (Exs. 212, 350-354). Myrj 45 and Sta-Soft contain as well other glycol esters of varying molecular weights (Atlas R. 729, 1416, 1462, 1470, 1473-1474, 1536, 1548, Ex. 101) including some of high and some of low molecular weights which cause injury when fed to test animals (Atlas R. 726, 1550, 1558-1561, 1636, 1642, 1645, 1714, 1721-1722, 1779). The exact amount of these deleterious substances present is unknown.

level of dosage was fed, which was not high enough to delineate the toxic potentials. Animals of only one sex were used. The number of animals was not great enough to permit sound conclusions to be drawn. The causes of certain observed deleterious effects were not properly investigated. The Administrator disagreed with the Atlas witnesses that the observed differences in growth rate, mortality, and pathology between control and test animals could be disregarded as "unimportant, not significant, or not connected with the feeding of the test substances" (Finding 41, Atlas R. 469-471).[12]

---

[12] Myrj 45 was tested on rats, rabbits, monkeys and dogs (Ex. 61 pp. 1-60). In the course of the life span study with two groups of 15 rats each, more than one-half of the animals died prematurely (Atlas R. 891) and at the end of the period there were 5 survivors in the control group but only 2 survivors in the test group (Atlas R. 891). This made it impossible to prepare meaningful growth charts for Myrj animals (Atlas R. 893). Two monkeys were studied, but one of these died of tuberculosis during the test (Ex. 61, pp. 6-7). Both monkeys lost weight. An experiment was started with five test and five control rabbits (Atlas R. 808). The experiment was stopped at 19 weeks because only one rabbit in the test group survived, the other four having been the victims of cannibalism (Ex. 61, pp. 28-30). No such fate befell the control animals, but Dr. Krantz attached no significance to it (Atlas R. 890), despite the facts that he had never before encountered cannibalism in rabbits (Atlas R. 898) and that rabbits are known to be vegetarian animals (Atlas R. 1274) unlikely to eat each other. In the test conducted on two dogs, one died of an infection (Atlas R. 1007).

Another investigator tested Myrj 45 and Sta-Soft (Atlas R. 2261). He used rats, six rabbits, three dogs, and five humans (Atlas R. 2471). Most of the experiments were for 12 weeks (Atlas R. 2262-2269). On cross-examination he agreed that more work was needed to test the trends developed by his experiments (Atlas R. 2456, 2457-2460, 2480-2481, Exs. 152, 164). In his rat tests, he found abnormal liver pathology (Atlas R. 2270-2273, 2362), and some abnormalities of other organs (Atlas R. 3210-3211). He disregarded this because no "con-

On the question of the metabolic fate of the chemicals when ingested into the body, the Administrator found a disagreement among investigators.[13]

---

sistent" pathology was seen. Out of nine test animals, two had tumor growths (Atlas R. 3212). There were no such growths in the controls. There was a "slight" tendency for reproduction performance to diminish (Atlas R. 2386). He had an exceedingly high mortality rate (Atlas R. 2369). In one study, 80% of the test animals (males) died as against 20% of the controls; 60% of the test females died as against 0% for the controls (Atlas R. 2364-2365, see also Atlas R. 2368). The causes of the deaths were infections or causes "not specifically diagnosed" (Atlas R. 2366). But Dr. Oser "doubts" that any deaths were due to the test diet (Atlas R. 2276). Only 3 rats on Sta-Soft survived more than 80 weeks of the test (Ex. 357).

In his rabbit experiment, one animal developed coccidiosis (Atlas R. 2309). There were no controls, so Dr. Oser attributed the abnormal liver pathology to causes other than the test material (Atlas R. 2314-2316). There were blood deviations, but he thought these unimportant (Atlas R. 2310-2311). He admitted that so few animals were used that any deviations could be attributed to chance (Atlas R. 2416-2417).

Dr. Oser's dogs also had abnormal kidney pathology (Atlas R. 2320-2324) and abnormalities of the gastrointestinal tract, but this again was thought to be due to outside causes and not the test diet (Atlas R. 2323-2324).

See also Ex. 201, a report made to C. J. Patterson Co., showing severe injury to golden hamsters from Sta-Soft.

[13] The question of metabolic fate of the compounds was considered important in deciding their harmlessness (Atlas R. 1929-1930, 2938). There was a possibility that the polyol might be converted into oxalic acid, forming urinary bladder stones comparable to those known to occur from diethylene glycol (Atlas R. 1083, 2010). The experts were in general agreement that it would be an undesirable effect to have the non-food polyol stored in the body for indefinite periods (Atlas R. 1935, 1984, 2146, 2431). Atlas sought to prove that the polyol was rapidly excreted and thus that no harm could come from the compounds (Atlas R. 764-765, 777-778, 786-787).

Atlas' key witness was Dr. Culver (Atlas R. 1040), who did recovery studies on Tween 80 and Myrj 45. He concluded, from results of analyses not made by him but by Atlas' laboratories (Atlas R. 1083-1084, 1088, 1141), that the polyol was almost completely excreted. Using Tween 80 on 3 patients, he

The Administrator noted that the record suggested the possibility that the softener may increase the susceptibility of animals to infectious disease organisms taken in with the food, but that the evidence was inadequate to supply the answer whether the chemical actually had the effect or whether, if so, it would be significant in human infectious diseases (Finding 42, Atlas R. 472-473).[14]

Having pointed out the softener's potentialities for harmful effect, and having explained in detail the deficiencies in the evidence on the safety issue, the Administrator concluded that despite the absence of definite evidence of past injury from poly-

---

claimed 100% recovery of the polyol. One patient, however, did not give the same results (Atlas 1090). This was disregarded, because it did not "fit" with the other three patients. On Myrj 45, six patients were tried (Atlas 1103-1104). Here two did not give complete recoveries (Atlas 1103-1104). They too were disregarded, and Dr. Culver reached his conclusion on the four "well controlled" cases (Atlas R. 1104-1106).

Dr. Shaffer, Glyco's expert, studied the fate of polyoxyethylene glycols used in Sta-Soft. His recoveries were not complete (Atlas R. 1826-1840, 1944, 2011, 2019). He concluded that the polyol from Sta-Soft undergoes some change in the body that cannot be explained (Atlas R. 1837, 2060, 2076-2078).

[14] Dr. Rene DuBos, of the Rockefeller Institute for Medical Research (Atlas R. 3154-3156), discovered that Tween 80, Tween 60, G-2144 and G-2124 (Myrj type products) were among the few surface active agents of a great many tested that would affect the growth pattern of tubercle bacilli (Atlas R. 3156-3159). Without these wetting agents the bacilli grow only in clusters and only on the surface of the growth medium (Atlas R. 3159). With the agents, the growth pattern is drastically changed and the bacilli grow throughout the medium in small clumps or as isolated individuals (Atlas R. 3159).

Dr. DuBos said that additional work would have to be done to determine whether these materials would have an effect on the course of tuberculosis in man or other animals (Atlas R. 3163, 3165).

oxyethylene monostearate, it was impossible to find that "there is no likelihood of injury from bread containing these substances in the amounts proposed . . . [if eaten] over a life span". Finally, on the basis of the whole record, he expressed his conclusion that it would not promote honesty and fair dealing in the interest of consumers to recognize polyoxyethylene monostearate as an optional ingredient in bread (Finding 42, Atlas R. 472-473).

The Administrator also filed a memorandum explaining that Atlas Powder Company's motion to reopen the record was denied because the supplemental data submitted to support it revealed that the investigations to establish safety were still incomplete in important respects (Atlas R. 482-484). The memorandum also explained why mono- and diglycerides were considered in separate classes from the Atlas product (Atlas R. 478-482). Mono- and diglycerides are closely related to natural fats; they had been used in food for at least 20 years; and the record showed no questions raised concerning their safety. (Atlas R. 478-479).[15] In addition, the use of glycerides could be so limited as to avoid deceptive bread softening while preserving their advantage as shortening (Atlas R. 484).

On petitions for review filed by Atlas and Glyco in the Court of Appeals for the Third Circuit, the order establishing the regulations was unanimously

[15] The Administrator found that mono- and diglycerides are harmless, but that a final decision on their safety could not be made until the full significance of their surface-active effects had been explored along the lines suggested by the Food Protection Committee (Finding 5, Atlas R. 459-461).

affirmed. A careful review of the whole record convinced the court that "the Administrator properly concluded that the safety of the questioned products had not been established" (Atlas R. 3292). The negative finding in that respect, combined with the affirmative findings as to "the lack of long term experience with daily human consumption of these products", "their complex and not wholly clear chemistry", "the alarm with which that chemistry was viewed by competent and disinterested scientific groups and the actual presence of toxic material even in very small quantities", the court said, justified "their rejection as an item of daily human diet until satisfactory affirmative proof of safety should be forthcoming" (Atlas R. 3292).

ARGUMENT

1. a. Glyco Products Co. (petitioner in No. 584) contends that the order here involved, fixing the standard of identity for bread, is invalid for the reason that Section 401 does not authorize the Administrator to forbid the addition of optional ingredients which do not affect the economic integrity of the food as such, in this case the characteristic of bread as bread. (Pet. No. 584, 8-9), 11-19.)

Aside from the fact that, under petitioner's own interpretation of the statute, an ingredient which may be poisonous and which has been found to deceive the public as to freshness, obviously does affect the characteristic of bread as bread, there is no merit in the contention. As the court below

pointed out, this argument is refuted by the plain language of the statute, and by the decision of this Court in *Federal Security Administrator* v. *Quaker Oats Company,* 318 U.S. 218. The clear language of Section 401 empowers the Administrator to permit or not permit optional ingredients. And as this Court said in the *Quaker Oats* case, at p. 232:

> The statutory purpose to fix a definition of identity of an article of food sold under its common or usual name would be defeated if producers were free to add ingredients, however wholesome, which are not within the definition.

See also 62 *Cases of Jam* v. *United States,* 340 U. S. 593, 598, where the holding was restated, this Court saying of the *Quaker Oats* decision:

> We sustained the regulations, holding that Congress had constitutionally empowered the Administrator to define a food and had thereby precluded manufacturers—or courts—from determining for themselves whether some other ingredients would not produce as nutritious a product.

That decision answers as well Glyco's second contention (No. 584, Pet. 19-20) that Section 401 is an unlawful delegation of legislative authority. There is an unbroken line of decisions, extending throughout the entire history of our constitutional form of government, holding that the Constitution does not forbid Congress to delegate to an adminis-

trative agency the task of implementing legislation by filling in the details.[16]

In Section 401 Congress described the legislative objective—the promotion of honesty and fair dealing in the interest of consumers. Congress prescribed the method of achieving that objective—the fixing and establishing of reasonable definitions and standards of identity for any food, under its "common or usual name", including the specification of the permitted optional ingredients. And Congress delegated the task of fixing the standards to the Federal Security Administrator. Only recently this Court reaffirmed a long line of decisions holding that general terms such as "excess profits," "just and reasonable rates" and "public interest, convenience or necessity" were proper standards for delegated legislation. *Lichter* v. *United States*, 334 U. S. 742, 785, 786. We think it clear that Section 401 contains a sufficiently definite standard for administrative action.

b. Atlas Powder Company (No. 610, Pet. 3-4, 12) argues that the Administrator exceeded his authority in excluding polyoxyethylene monostearate on a purely negative finding that its safety had not been established (No. 610, Pet. 8-20).

The entire argument on this point, based on a single sentence in finding 42 (Atlas R. 473), ignores the whole of findings 40 and 41 and the con-

[16] It is clear that Congress may confer upon the executive branch the power to fix standards of a technical nature with respect to which a statute is to apply. See, for example, *Buttfield* v. *Stranahan*, 192 U. S. 470, where an administrative official was lawfully authorized to fix uniform standards of purity for imported tea.

text of finding 42 itself (Atlas R. 467-473). Actually, the Administrator made a series of affirmative findings that raised the gravest doubts about the safety of polyoxyethylene monostearate. Among these were the facts that the chemical contains residues of poisonous impurities, is closely related to known poisons, contains a non-food portion with an unknown metabolic fate in the human body, has no long standing food use indicating its safety, and has been inadequately tested in the laboratory to show whether it is safe. What the Administrator found on this record was that there were signs tending to show injury to the test animals, but that the experiments were so poorly planned and conducted that a "definite" scientific judgment could not be reached as to whether injury was attributable to the chemical.

The Court of Appeals painstakingly appraised all of the evidence. The court held that the exclusion of the chemical was not grounded alone on a negative finding, but that the "negative finding was given effect in the light of a number of significant facts" (Atlas R. 3292).[17]

Although conceding that the Administrator could bar a chemical from a standard of food if there were "an affirmative finding that its unsuit-

---

[17] Atlas contends that an "inherently impossible" burden was placed upon it, citing *Anniston Mfg. Co.* v. *Davis*, 301 U. S. 337, 352-354. But that case holds that "Impossibility of proof may not be assumed"; whether it exists must await until all the facts are in. The Administrator has specified the obvious defects in petitioner's safety evidence. It cannot now be said that it will be impossible to prove whether the chemical is safe.

ability has been proven," Atlas contends that it cannot be barred on any finding less affirmative (No. 610, Pet. 13-17). To bolster the point, the argument is made that because Congress enacted special provisions relating to the safety of new drugs (No. 610, Pet. 13-14),[18] and now has under consideration new legislation dealing with chemical additives to food (No. 610, Pet. 17-18),[19] the implication is that

---

[18] Petitioner in No. 610 (Pet. 13) implies that the new drug section and the food sections were studied together throughout the 5 year legislative history of the Act. The fact is the new drug provisions had their genesis in the Elixir Sulfanilamide tragedy which occurred in September and October 1937. Sen. Res. 194, 75th Cong., 2d Sess., called upon the Secretary of Agriculture for a full report. The report was submitted November 25, 1937. Dunn, *Federal Food, Drug, and Cosmetic Act, A Statement of Its Legislative Record*, 1316-1327. The revision of the statute had been under consideration in Congress since 1933. The Federal Food, Drug, and Cosmetic Act, with the new drug provisions inserted in Section 505, was signed by the President on June 25, 1938.

This Section prohibits the interstate distribution of all new drugs before they have been adequately tested for safety. There is no comparable provision under the food chapter of the Act. Chemicals that have not been adequately tested for food use can be introduced into the food supply without advance clearance with the Administrator, as Atlas did. But this does not imply that the Administrator must disregard safety questions in carrying out the mandate of Section 401 to "promote honesty and fair dealing in the interest of consumers."

[19] See *Wong Yang Sung* v. *McGrath*, 339 U. S. 33, 47-48, where the Court refused to draw an inference from proposed legislation. But, in any event, a report of the House of Representatives Committee To Investigate the Use of Chemicals in Foods, stated: "Section 401 of the Federal Food, Drug, and Cosmetic Act authorizes the Federal Security Administrator to define and standardize foods for the purpose of promoting honesty and fair dealing in the interest of consumers. This empowers him to determine whether a chemical proposed for use in a standardized food has been demonstrated to be safe (H. Rep. No. 2356, 82d Cong., 2d Sess., 24).

no authority was given the Administrator by Section 401 to consider questions of safety.

It is obvious, however, that considerations of safety may enter into the Administrator's judgment; for "fair dealing" with the consumer requires protection of his health at least as much as protection of his pocketbook. If it is unfair to put before the consumer foods whose economic worth he cannot properly judge, it is certainly no less unfair to offer him foods whose safety neither he nor the best qualified scientists can judge.[20]

And once it is admitted that safety questions can be considered, there is no basis for the introduction of an artificial rule that the Administrator cannot take action to exclude a suspect chemical unless the proof shows definite past injury from it. If an ingredient may be excluded from a standard when proved harmful, why may not the Administrator find unfairness in exposing the public to a chemical that is closely related to known poisons and that has not yet been proved safe?

---

[20] It is also obvious that the power to fix standards was intended to supplement and implement the other provisions of the Act. Cf. the *Quaker Oats* decision at pp. 230-231. There is thus no merit in the argument by both Atlas (No. 610, Pet. 15, 17) and Glyco (No. 584, Pet. 21-24) that these regulations are invalid because they would allow the Administrator to avoid a judicial contest in which he would have the burden of proving that polyoxyethylene monostearate is a poisonous and deleterious substance, Sec. 402(a), 21 U.S.C. 342(a), or would make bread appear better or of greater value than it is, Sec. 402(b), 21 U.S.C. 342(b). The food standards provisions were intended by Congress as a means of maintaining the integrity of the food supply (H. Rep. No. 2139, 75th Cong., 3d Sess., 2 (1938)). The integrity from a toxicological standpoint is as important as economic integrity.

The language of the statute and ordinary common sense require that regulations not be issued which place the Administrator's stamp of approval on chemicals of doubtful safety proposed for addition to the most common staple in our diet, thus in effect making the public unwitting "guinea pigs."

In *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218, 227-228, 232, this Court held that a wholesome and beneficial ingredient could be excluded from the standard because of an indirect affect on public health arising from confusion in marketing. *A fortiori,* the statute permits the exclusion of suspect ingredients, the future effects of which are unknown.

As this Court pointed out in the *Quaker Oats* case (p. 228) "the exercise of the administrative rule-making power necessarily looks to the future." See also *American Airlines, et al.* v. *Civil Aeronautics Board,* 192 F. 2d 417, 421 (C.A.D.C.) where the court said:

> Since regulatory functions must necessarily contemplate the future, the law which is involved in those functions must be realistic enough to permit that scope. So, when a prospective rule is required to be upon evidence, that evidence must be construed to include estimates, or forecasts, or opinions, on future events. At the same time, governmental permissions for the future cannot be fashioned from pure fantasy, speculation devoid of factual premise. * * *

So long as the Administrator reasonably entertained a doubt as to the safety of the chemicals

when used in bread over a life span, he could not find that a regulation permitting their use would promote honesty and fair dealing in the interest of consumers.[21]

2. Atlas Powder Company's second point (No. 610, Pet. 20-22) is that the Court of Appeals upheld the Administrator's finding, through which he limited the use of mono- and diglycerides to not more than 20% of the shortening in bread to avoid deceptive softening effects (Atlas, R. 460-461), despite a total absence of evidence to support it.

An examination of the Court of Appeals' opinion reveals, however, that there was evidence to support the finding. Atlas interpreted this evidence one way. The Administrator interpreted it another (Atlas R. 3295). The court recognized that the proper interpretation of the evidence was arguable, but held that the Administrator was not arbitrary in placing his interpretation upon it (Atlas R. 3295).

This Court, in *Universal Camera Corp.* v. *National Labor Relations Board*, 340 U.S. 474, 491, and *National Labor Relations Board* v. *Pittsburgh S. S. Co.*, 340 U.S. 498, 502-503, has emphasized the finality of Court of Appeals' action in deter-

[21] Glyco makes a contention (No. 584, Pet. 24-25) that if the Administrator excludes an ingredient because the proof of its safety is inadequate, he must spell out in his findings of fact based on the record "a specific standard of adequacy." Clearly the Administrator was not required to explain on the record the fundamentals of the safety testing of chemicals proposed for use in foods. Cf. *Market Street Ry. Co.* v. *Railroad Commission*, 324 U.S. 548, 560-561. Here the Administrator has detailed the gross deficiencies in the proof of safety (Findings 41-42, Atlas R. 468-473). We respectfully submit that nothing more was required.

mining whether a finding is supported by substantial evidence. This Court does not make an "independent review of the review" below, and there is nothing here to indicate that the Court of Appeals either misapprehended or misapplied the *Universal Camera* rule. On the contrary, it is plain that the court conscientiously performed its review function.

Moreover, it is difficult to see how petitioner could be helped even if there were error, which we do not concede, in sustaining the finding. It would at best lead to the exclusion of mono- and diglycerides or reversal for the fixing of another limit on their use. It could not be used as a means to require the admission of polyoxyethylene monostearate into the standard. As the Court of Appeals pointed out, the many differences between mono- and diglycerides and polyoxyethylene monostearate justified their classification into separate groups (Atlas R. 3292-3293, 3294-3295).

3. The final contention made by Atlas (No. 610, Pet. 23-27) is that, contrary to the plain language of Section 701(f)(2), 21 U.S.C. 372(f)(2), the Court of Appeals abused its discretion in failing to make an independent determination whether the new evidence described in Atlas' motion for leave to adduce additional evidence [22] was material.

Despite a clear statement by Judge Hastie (Atlas

---

[22] The record contains no such motion. All offers of new evidence were made to the Administrator. Atlas complained that the Administrator abused his discretion in refusing to reopen the record.

R. 3298) that a *de novo* examination of the proffered evidence had been made, and had led the court to agree with the Administrator that it was insufficient to change the result and thus inadequate to require reopening, Atlas insists that the court made no such independent review.

The Atlas contention that the court should review *de novo* the Administrator's denial of the motion to reopen was an afterthought. In the petition for review (Atlas R. 3248-3249, para. 32-35), Atlas complained that the Administrator had acted unlawfully in refusing to reopen the record. After respondent placed reliance on *Interstate Commerce Commission* v. *Jersey City,* 322 U.S. 503, 514-519, urging that the question presented to the Court was whether the Administrator had abused his discretion, Atlas insisted it was entitled to a *de novo* review of the materiality of the new evidence. Though the Court of Appeals agreed that reopening is normally a matter for the Administrator's discretion—particularly where all of the alleged new evidence has been submitted to him and he has expressed his expert judgment that it is insufficient to change the result already reached on an extensive record—the court gave Atlas an independent review.

What Atlas is really contending is that the Court of Appeals erred when it accepted the Federal Security Administrator's statement that the Food and Drug Administration's experimental data was incomplete and thus indecisive on the safety issue. Atlas characterizes this statement, officially made

by a responsible government official, as a "hearsay representation of a party" (No. 610, Pet. 26).

It is respectfully submitted that the court below properly accepted the government official's statement as to the status of the alleged experimental work, without insisting that a group of scientific work sheets be certified to it for appraisal even before the scientists engaged in the experiments were ready to formulate conclusions on them. The latter course would have had the effect of enlarging the scope of judicial review, contrary to this Court's decision in *National Labor Relations Board* v. *Donnelly Garment Co.*, 330 U.S. 219, 233-237.

CONCLUSION

For the foregoing reasons, we respectfully submit that the petitions for writs of certiorari should be denied.

ROBERT L. STERN,
Acting Solicitor General.
WARREN OLNEY III,
Assistant Attorney General.
BEATRICE ROSENBERG,
Attorney.

WILLIAM W. GOODRICH,
Assistant General Counsel,
Federal Security Agency.
MARCH 1953.

☆ U. S. GOVERNMENT PRINTING OFFICE: 1953 246030 1314

IN THE

Supreme Court of the United States

OCTOBER TERM, 1952

No. 610

ATLAS POWDER COMPANY, a Corporation, *Petitioner,*

v.

OSCAR R. EWING, Federal Security Administrator, *Respondent.*

On Petition For a Writ of Certiorari to The United States Court of Appeals For The Third Circuit

PETITIONER'S REPLY TO RESPONDENT'S BRIEF IN OPPOSITION

I.

Our petition raises the novel and important question whether the Congress intended to authorize the Federal Security Administrator to ban the use of an established food product on a negative finding that suitability had not been proven, rather than an affirmative finding of unsuitability.

The Administrator's statement of the questions presented is framed as if he did not act on a negative finding at all (Res. 2-3).* The Administrator's Brief attempts

* Our Petition for Certiorari is referred to as (Pet. —); Respondent's Brief in Opposition is referred to as (Res. —).

to create the impression that he affirmatively found "the gravest doubts" about the safety of Myrj 45 (Res. 21).

The short answer is that the Administrator's findings do not include any statement that he had "the gravest doubts" about the safety of Myrj 45. The Administrator's finding which is his own summary of the so-called affirmative evidence reads as follows:

> "Although the record shows no definite evidence of injury from the use of . . . polyoxyethylmonostearate in amounts in which they are likely to occur in the diet from their use in bread, the results of the pharmacological tests reported do not warrant the conclusion that there is no likelihood of injury from bread containing these substances in the amounts proposed to persons consuming it continuously over a life span." (R. 473).

This negative finding was the Administrator's ultimate description of the total factual situation and the conclusion which he drew from the facts. It represented the most that in his opinion the record permitted him to say about the safety of Myrj 45. The doubt-raising "affirmative findings" referred to by the Administrator's Brief (Res. 21) were merged into the ultimate finding, which was negative in form. The negative finding was not mere redundancy, nor was it an accident. The Administrator had been reviewing a record closed for almost three years. He had been reviewing exceptions to his tentative findings —which included a similar but somewhat different negative finding on safety*—for over a year and a half. In the light of this history, the cautiously worded negative finding cannot be interpreted as the equivalent of an affirmative finding of unsuitability on safety grounds,

---

* The tentative finding was: "Although there has been no definite evidence of injury from the use of . . . polyoxyethylene monostearate in amounts in which they are likely to occur in the diet from their use in bread, the investigational work does not definitely establish their safety, and the record does not permit a conclusion that bread containing them is safe for continuous use over the human life span." (R. 15).

i.e., that there is a "likelihood of injury". If the Administrator had thought the record showed a "likelihood" of injury, he would have so found.

Further proof that the Administrator did not think he could so find, and does not think so today, is contained in a speech delivered by the Honorable M. R. Stephens, Associate Commissioner of Food and Drugs, in Chicago on March 4, 1953, before the Society of Bakery Engineers. A copy of the Federal Security Agency's press release containing the full text of this speech has been filed with the Clerk of this Court. Mr. Stephens was discussing the bread standard, and the pending cases challenging the validity of the standards.* He then continued:

> "The adjudication of these cases should settle once and for all any question about the use of that chemical [polyoxyethylene monostearate] in the standardized breads. Th re exists no provision in the law however under which this chemical can be automatically excluded from unstandardized products. Even though we do not regard the evidence of safety as adequate, we cannot exclude it from the unstandardized products *until we can produce evidence to prove in Court that its use may be injurious to health.*" (p. 2, emphasis added).

Mr. Stephens' statement of the law as applied to unstandardized foods states our point exactly, as applied to standardized foods. We maintain that an established product cannot be excluded from a food standard on the issue of safety "until" the Administrator finds on "evidence" in the record at least as much as he would have to *prove* in a court action based on the substantive provisions of the Act relating to safety (Pet. 15-17). That is to say, he must

* In addition to No. 584 and No. 610, now pending before this Court, another manufacturer of polyoxyethylene monostearate, Research Products Co., has filed a petition for review of the Administrator's order in the Court of Appeals for the Eighth Circuit. Briefs have not yet been filed, but a Government motion to affirm is pending.

find at least "that its use may be injurious to health."* The Administrator could not make and did not make any such finding here.

To the extent that the Administrator admits having relied on a negative finding, he has chosen to meet our contention that he lacks power to do so by paraphrasing it into two different contentions, neither of which we made.

The Administrator first suggests we have argued that he has no authority to consider questions of safety in a food standard proceeding (Res. 22-23). We did not and do not so contend. The Administrator next suggests we have argued that a finding of definite past injury is essential to exclude an ingredient from a food standard (Res. 23). We did not and do not so contend. Our argument is simply that he acted on a negative finding; and it is the legality of that action which we contest.

The Administrator's reliance on *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218 (1943), does not solve his problem. His point is that because *Quaker Oats* approved exclusion of a concededly wholesome ingredient, exclusion of "suspect ingredients" is *a fortiori* within his power (Res. 24). If *Quaker Oats* had approved exclusion on a negative finding, the Administrator's point would be well taken. But exclusion there was based on an affirmative finding that the ingredient "would tend to confuse and mislead consumers" (318 U.S. 218, 223), not a negative finding that the evidence failed to prove the ingredient "would not tend to confuse and mislead consumers."**

---

* In this context, of course, "may" connotes probability, rather than possibility. *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 658 (1914). The phrase "may be injurious" is therefore equivalent to "likelihood of injury."

** The Administrator's only direct challenge to our demonstration that Congress did not intend and did not authorize the use of negative findings in food standard proceedings is to quote from a 1952 report of the House of Representatives Select Committee to Investigate the Use of Chemicals in Foods, written 14 years after the statute being construed was enacted in 1938. (Res. 22, n. 19).

The Administrator has made no attempt to disprove the great importance of the negative finding issue as a matter of general administrative law. In addition to the reasons which we have cited (Pet. 8-11), it has recently come to our attention that another administrative agency is currently making use of negative findings under circumstances in which their authority to do so may be questionable. In *United States ex rel. Dolenz* v. *Shaughnessy*, 200 F. 2d 288 (2 Cir., 1952), a divided Court of Appeals upheld an order dismissing a writ of habeas corpus brought by an alien whose deportation had been ordered. The Court held that the Attorney General's delegate did not abuse his discretion in ordering deportation on the ground that he did not find that the alien would be subjected to physical persecution if deported to Yugoslavia. Judge Charles E. Clark, dissenting, stated that ". . . the finding here in question is inadequate, since it is carefully negative in form." 200 F. 2d 288, 292. A Petition for Writ of Certiorari is pending before this Court (No. 576, October Term, 1952).

In the *Dolenz* case, the statute involved may conceivably be at least susceptible to interpretation as an explicit Congressional authorization of exclusion on the basis of a negative finding. In the instant case, the food standard section of the statute cannot be construed to authorize a negative finding explicitly and no such authorization can be implied in view of the contrasting language of the new drug provisions of the same statute as well as the pendency of proposed legislation designed to apply the new drug principle to food.

No matter how this statement may be interpreted, this Court has repeatedly refused to accept the opinion of members of a subsequent Congress about legislation enacted by a previous Congress "as authoritative guides to the construction of" that legislation. *United States* v. *United Mine Workers*, 330 U.S. 258, 281-282 (1947); *Fogarty* v. *United States*, 340 U.S. 8, 13-14 (1950). These precedents are particularly applicable to a Committee expression where, as here, no member of the Committee expressing the opinion was a member either of the Committee which drafted the legislation or even of the Congress which enacted it.

The essential unreviewability of negative findings poses a novel issue of administrative law which has far reaching implications. Whether a Congressional intent to cut down judicial review should be implied when Congress has not so directed expressly is a question which this Court should resolve.

II.

In our petition we also contended that the Court of Appeals had approved an important finding made entirely without supporting evidence (Pet. 20-22). The Administrator answers that an "examination of the Court of Appeals' opinion reveals, however, that there was evidence to support the finding." (Res. 25). However, the Administrator's brief makes no citation to any record evidence supporting his finding that a "non-deceptive" level of use existed for the mono- and diglycerides. As we have pointed out, there was no such evidence (Pet. 21). Furthermore, a careful analysis of the Court of Appeals' opinion on this point shows that the Court of Appeals did not and could not say that this finding was supported by substantial evidence (See Pet. 21-22). The Court of Appeals sustained the conclusion on the theory that it was an allowable exercise of administrative judgment (R. 3294-95)—a judgment unsupported by any facts (Pet. 20-22). This was clear error, which is not concealed by the Administrator's reference to the Court's opinion.

The Administrator further argues that if the Court of Appeals did commit error in this respect, we cannot complain of it because, he says, "[i]t could not be used as a means to require the admission of polyoxyethylene monostearate into the standard." (Res. 26).

This is hardly an answer. It was not the function of the Court to direct the Administrator to include our product in the standard. But, where agencies act without any supporting evidence and, in the process, formulate arbitrary discriminations, Courts have the duty to reverse for the

taking of corrective measures. In this case the corrective measure would be a determination by the Administrator whether, on the issue of deception, there is a basis (record evidence alone considered) to distinguish between our products and the competing mono- and diglycerides.

III.

We also argued in our petition that the Court of Appeals ignored prior decisions of this Court by failing to make an independent determination of the materiality of evidence which we sought to have adduced in a reopened hearing, pursuant to Section 701(f)(2) of the Act (Pet. 23-27). The Administrator concedes that all the Court of Appeals had before it on the question of the materiality of tests conducted by the Food and Drug Administration itself on our product was a statement in the Administrator's brief that such evidence was not material. The Administrator objects to our characterizing this as "a hearsay representation of a party" (Res. 27-28). We adhere to that characterization. If counsel for Atlas had told the Court of Appeals that Atlas possessed evidence proving beyond any doubt that its products were absolutely safe, and if the Court of Appeals, relying on this representation, had ordered the Administrator to reopen the hearings, the Administrator would be here today making the same complaint that we make and he would be entitled to the same relief to which we are entitled. The Government's *ipse dixit* is no more conclusive than anyone else's. Cf. *United States* v. *Packer*, 200 F. 2d 540, 542 (2 Cir., 1952), *cert. granted*, 21 U.S.L.W. 3244 (1953).

There is some suggestion by the Administrator that we never invoked the Court of Appeals' power under Section 701(f)(2) of the Act to order the production of additional evidence in a reopened hearing (Res. 26). This ignores both the prayer for relief in our Petition for Review (R. 3249-3251) and the assumption by the Court of Appeals that Section 701(f)(2) had been invoked (R. 3297-3298).

Conclusion

We respectfully renew our prayer that our petition be granted.

Oscar Cox,
1210 18th Street, N.W.,
Washington 6, D. C.,
Attorney for Petitioner.

C. C. Gammons,
Kenneth E. Mulford,
Roger R. Horton,
Delaware Trust Co. Bldg.,
Wilmington, Delaware.

Ezekiel G. Stoddard,
Lloyd N. Cutler,
Louis F. Oberdorfer,
Herbert L. Packer,
William R. Perlik,
1210 18th Street, N.W.,
Washington 6, D. C.
Of Counsel.